UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

PATRICIA S. PEREZ, individually and on behalf of her minor child I.R., Plaintiff, -against- NEW PALTZ CENTRAL SCHOOL DISTRICT and DR. MARIO FERNANDEZ, in his official capacity as the principal of the New Paltz High School, Defendants.	Index No. 1:21-CV-706 (DNH/CFH) **COMPLAINT**

Plaintiff, by and through her undersigned counsel, alleges on personal knowledge as to herself and upon information and belief as to all other matters:

PRELIMINARY STATEMENT

1. Plaintiff is a parent and represents her minor child who has been administered all vaccines required under New York law to attend school with the exception of one dose of a tetanus, diphtheria and pertussis containing vaccine and one dose of a polio vaccine. Plaintiff has made an informed parental decision to not administer additional doses of these vaccines to her child based on her intimate knowledge of her child, her child's medical history, and these products, including because these vaccines (unlike others) do not prevent infection and transmission of the target pathogen, and because her child has immunity (as confirmed by antibody tests) to these pathogens. Nevertheless, Defendants intend to exclude this child from school exclusively because of her failure to receive one dose of each of these vaccines.

2. Conditioning the provision of a constitutionally mandated right to an education on the injection of these products, and overriding a parent's informed medical decision, impinges upon her and her child's fundamental constitutional rights to bodily integrity, parental choice,

informed consent, free exercise, and the substantive due process right to life and liberty under the United States Constitution and the New York Constitution, and the right to an education under the New York Constitution.

3. The only way the State of New York can justify impinging on these constitutional rights is if it can demonstrate both a compelling state interest to exclude the child from school and that exclusion is the least restrictive means to achieve the compelling interest. Courts have previously recognized that New York's desire to control infection from student-to-student can create a sufficient compelling state interest in order to trump some of the foregoing constitutional rights. However, that compelling interest to control infection from student-to-student is absent with regard to vaccines at issue in this case.

4. The pertussis vaccine cannot form the basis of a compelling interest to control infection because it does not prevent the vaccinated child from becoming infected and transmitting pertussis. *See, e.g.,* Vaccine (2018) https://www.ncbi.nlm.nih.gov/pubmed/29180031 ("neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the [pertussis] pathogen") *and* Frontiers in Immunology (2019) https://pubmed.ncbi.nlm.nih.gov/31333640/ ("aPVs [acellular pertussis vaccines] … can prevent disease but cannot avoid infection and transmission"). Pertussis vaccines reduce the symptoms of pertussis, but they render those who are vaccinated susceptible to becoming repeatedly infected with pertussis. Given that the pertussis vaccine does not prevent student-to-student transmission, Defendants cannot rely on their desire to control infection to create the necessary compelling state interest to deny Plaintiff and her child's constitutionally protected rights. Therefore, requiring injection of this product into Plaintiff's child over her objections is an unjustifiable infringement on their constitutional rights. (*Infra* First Cause of Action.)

5. The compelling state interest to prevent transmission of an infection is also absent with regard to vaccination for diphtheria. The diphtheria vaccine does not prevent a student from becoming infected nor does it stop the infected student from transmitting the infection to others. Instead, the vaccine is only designed to create antibodies to a toxin sometimes released by the diphtheria bacteria that can cause the symptoms associated with the infection. *See, e.g.*, American Journal of Diseases of Children (1972) https://www.ncbi.nlm.nih.gov/pubmed/5026197 ("Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection.") Because the diphtheria vaccine does not prevent student-to-student transmission of the infection, Defendants again cannot rely on their desire to control infection as a means to create the necessary compelling state interest to deny Plaintiff and her child's constitutionally protected rights. (*Infra* Sixteenth Cause of Action.)

6. The compelling state interest to prevent transmission of an infection from student-to-student is also absent with regard to vaccination for tetanus because tetanus is not contagious from person-to-person. *See, e.g.*, https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html ("Tetanus is not contagious from person to person.") For this reason, Defendants again cannot rely on their desire to control infection from student-to-student to create the necessary compelling state interest to deny Plaintiff and her child's constitutionally protected rights. (*Infra* Twenty-Fourth Cause of Action.)

7. The compelling state interest to prevent transmission of an infection from student-to-student is also absent with regard to vaccination for polio because the vaccine exclusively used in the United States for polio for the past two decades, inactivated polio vaccine ("**IPV**"), does not prevent a student from becoming infected with the polio virus nor does it stop the infected student from transmitting the infection to others. Instead, IPV only potentially prevents a person injected

with this vaccine from potential complications from the polio virus. This is because the polio virus proliferates in the intestines and is transmitted through fecal to oral contamination, but IPV generates antibodies in the blood, not in the intestinal tract. *See* http://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/ ("IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces … IPV does not stop transmission of the virus.") Because IPV does not prevent infection from student-to-student, Defendants again cannot rely on their desire to control infection as a means to create the necessary compelling state interest to deny Plaintiff and her child's constitutionally protected rights. (*Infra* Thirty-Second Cause of Action.)

8. Even if these vaccines could prevent infection and transmission, which is not the case, Plaintiff's child already has immunity to all of the pathogens for which these vaccines are intended to create immunity. Her antibody levels for each pathogen exceeds the antibody levels deemed to confer immunity in the clinical trials relied upon to license these products. (*Infra* § IV.B.)

9. In addition, the empirical evidence shows that the number of cases of each of these infections did *not* decline after each was required under New York State law for attending school. (*Infra* § II.) Therefore, even if they did prevent infection and transmission, and Plaintiff's child was not already immune, there is no evidence that these vaccines are necessary to prevent Plaintiff's child from infecting other children. As such, Defendants' rational for excluding this child from school is fatally flawed down to its very core.

10. On the other hand, it is a well-established and indisputable fact that these vaccines can cause serious injury and death. (*Infra* § IV.A.) For example, the DTP vaccine – which has

the same tetanus and diphtheria components still used in the United States but more pertussis antigen – is currently the most commonly used vaccine in the world and was used for generations in the United States until around 2000. Nonetheless, the first natural experiment to ever compare the death rate between those receiving this vaccine during the first six months of life with children receiving no vaccines during this period was published in 2017. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/). The result of this study was that the vaccinated children died at *ten times* the rate of the unvaccinated children. These children were dying from other infections that nobody had associated with vaccination. The study's authors, renowned vaccine experts, concluded that this indicated that the vaccine, while deemed protective against tetanus, diphtheria and pertussis, had increased the recipients' susceptibility to other infections so significantly as to result in death.

11. This study notwithstanding, the long-term safety effects of tetanus, diphtheria and pertussis containing vaccines as well as the current polio vaccine are chronically under tested. Over the last three decades, the Institute of Medicine has repeatedly found that the medical community has failed to perform the necessary studies to identify whether a host of different serious and commonly claimed injuries and health conditions are, or are not, caused by vaccines for these pathogens. (*Infra* § IV.A.) Not only have studies not been conducted to assess whether commonly claimed injuries from these vaccines are caused by these products, the Institute of Medicine has also repeatedly warned that the studies needed to identify which children are at risk of serious harm have not been conducted. (*Id.*)

12. There are two major pharmaceutical companies that sell all tetanus, diphtheria and pertussis vaccines used in the United States – GlaxoSmithKline plc ("**GSK**") and Sanofi S.A. ("**Sanofi**") and only one that sells the current polio vaccine – Sanofi. Unlike most drugs, these

vaccines were *not* licensed based upon a placebo-controlled clinical trial. Furthermore, the safety review duration in these trials were far shorter than those for major drugs. For example, GSK's diphtheria, tetanus and pertussis vaccine was licensed based on a clinical trial that had a safety review duration of only 30 days after injection. (*Infra* § IV.B.)

13. After licensure, GSK and Sanofi must include in the package insert for their products – based on the post-licensure experience with the product – "*only* those adverse events for which there is some basis to believe there is a *causal* relationship between the drug and the occurrence of the adverse event." 21 C.F.R. 201.57 (emphasis added.) The package inserts for these vaccines include over one hundred serious conditions reported by GSK and Sanofi. (*Infra* § IV.) However, the scope and frequency of these injuries are unknown because, as noted, studies have not even been conducted to determine whether there is or is not an actual causal relationship between these vaccines and almost any of these serious events. (*Infra* § IV.C.)

14. Because of the dangers posed by vaccines, Congress enacted the National Childhood Vaccine Injury Act of 1986 (the "**1986 Act**"), which granted vaccine manufacturers (and any medical personnel that administers a vaccine) immunity from liability for injuries caused by these products. (*Infra* § IV.A.) Vaccines are the only products in the United States that have such immunity. No less an authority than the United States Supreme Court has stated that Congress thought this immunity was necessary because the damages caused by tetanus, diphtheria and pertussis containing vaccines far exceeded even the significant revenue from these products. As the Supreme Court explained: "by the mid-1980's … the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011). This

immunity creates a moral hazard for pharmaceutical companies and also means that product liability lawyers play no role in ensuring the safety of vaccines.

15. With virtually all pharmaceutical products, there are benefits but there are also risks. These vaccines are no exception. This is why the cornerstone of medical ethics is informed consent, a principle which is also a long recognized, fundamental, civil and human right. Informed consent requires conveying the risks and benefits of a medical procedure or pharmaceutical product to a patient and obtaining un-coerced consent. *See, e.g., Rivers v. Katz*, 67 N.Y.2d 485, 494 (1986) ("fundamental right to make decisions concerning one's own body"); *The Nuremberg Code* (1947) ("The voluntary consent of the human subject is absolutely essential. This means that the person…[is] able to exercise free power of choice, without the intervention of any element of…coercion."). Nonetheless, New York legislators have removed the concept of informed consent for any parent that wants their child to attend school in this state without injecting the vaccines at issue in this complaint.

16. The deprivation of these rights is particularly harmful here because Plaintiff has serious medical concerns in administering the vaccines at issue. I.R. suffered various auto-immune dysfunctions as an infant. She presented with many allergy symptoms such as blotchy skin, folds under her eyes, and she scratched incessantly. At 18 months, I.R. exhibited central nervous system dysfunction and was taken to various allergy specialists. I.R. now lives with and is treated for diagnostic code 299, or "other nervous system disorder." Plaintiff avoids any situation that may further disrupt I.R.'s immune or central nervous system.

17. Despite the medical concerns with providing Plaintiff's daughter the vaccines at issue, under New York law, a child can only obtain a medical exemption to attend school without being administered the vaccines at issue if the child has already had anaphylaxis (life threatening

allergic reaction) or encephalopathy (brain damage) from a prior dose of that same vaccine. (*Infra* § VI.) Meaning, to attend school in New York without these products, a child needs to have almost died or suffered brain damage following a prior dose of the same vaccine. No medical exemption to further doses is permitted, even when a child suffers any of the other over one hundred reactions GSK and Sanofi have disclosed may be causally related to their tetanus, diphtheria, pertussis or polio vaccines. Nor can Plaintiff's child obtain a medical exemption despite the clear medical need for same. (*Infra* § VI.)

18. The parents of children who experience or have reason to conclude will experience a serious reaction or health condition after receiving a vaccine, like Plaintiff here, typically turn to the medical community to heal their children. When modern medicine cannot help, these parents often turn to a higher authority and their beliefs typically restrict them from engaging in conduct they believe may harm their child. Up until June 2019, these parents could claim a religious exemption for further vaccination. This exemption therefore also had the benefit of creating a release valve for the gap in scientific knowledge with regards to tetanus, diphtheria and pertussis containing vaccines, the polio vaccine, and the treatment of immune, neurological and other issues arising after receiving multiple injections of these products. Nevertheless, as of June 13, 2019, the New York legislature eliminated the right to claim a religious exemption for these products in order to attend school. (L. 2019, ch. 35.)

19. Given that a medical exemption is nearly impossible to obtain, and the religious exemption no longer exists, Plaintiff and her child now cannot avoid GSK and Sanofi's tetanus, diphtheria and pertussis containing products or Sanofi's polio vaccine if she wants to attend school in New York. Thus, Plaintiff's constitutionally protected rights to make an informed decision regarding bodily integrity of her child has been taken away from her. The absence of any effective

exemptions likewise deprives Plaintiff of her rights to parent her child and the substantive due process right to life and liberty.

20. Plaintiff's informed decision to not give an additional dose of a tetanus, diphtheria and pertussis containing vaccine and an additional dose of the polio vaccine is admittedly unpopular. As is often the case when constitutional rights are taken away, the drive to require vaccination of every student without exception has been driven by a fervent zeal on the part of certain portions of the population. There is an ongoing public pressure campaign to denounce anyone who questions any aspect of the vaccine program. Major social media platforms, such as Facebook, increasingly censor personal stories of parents describing their child's vaccine injury, labeling such posts as false information. Amazon has delisted books and movies that raise any concern regarding vaccines. There is even a drive to categorize public statements raising concern regarding vaccine products as hate speech and to label groups raising these concerns as hate groups.

21. It is respectfully submitted that it is precisely when those elected by the majority pass laws affirming majority views that constitutional rights matter most. This is especially true when the majority takes away rights from a minority that has been demonized and marginalized for their views. It is in those moments that the courts give life and meaning to these constitutional rights and safeguards. Not only to protect the minority, but the principles in that founding covenant that protect all Americans.

22. The assumptions and popular views about vaccine products have stifled the ability for most people – even otherwise intelligent and analytical individuals – to rationally and objectively consider these products. Plaintiff therefore respectfully asks that all preconceived notions regarding these products be set aside. That the dehumanization of Plaintiff and her child

be set aside. That the general ethos that individuals who make a medical decision to not inject their children with this product are not worthy of rights, to send their children to school, to practice in certain professions, to be part of civil society, all be set aside. That only proven statements be considered.

23. Plaintiff appreciates that she is requesting the Court review something that is currently considered beyond reproach. Many consider it off limits to even request to see the evidence which underpins claims regarding any vaccine because the science is purportedly "settled" and therefore asking for proof undermines this presumption. However, it is for this precise reason that this Court must, to carry out justice, cautiously examine the proof for any claim regarding the vaccines at issue in this action. This Court expertly and unbiasedly tackles complex factual matters every day and it is respectfully requested that there not be any special treatment accorded to the liability-free but not risk-free products at issue in this complaint because of the mythological status and mental sway vaccines appear to hold in the minds of the majority.

24. For these reasons, and those discussed below, Plaintiff respectfully seeks to enjoin Defendants from enforcing Public Health Law Section 2164, to the extent it requires vaccination for tetanus, diphtheria, pertussis and polio to attend school in New York, as well as declaratory relief regarding the legality and constitutionality of this requirement.

PARTIES

25. Plaintiff Patricia Perez is the mother of I.R. Ms. Perez graduated from Cornell University with a B.S. in Environmental/Organizational Psychology and thereafter obtained her Juris Doctor and has worked as an attorney for Paul Weiss Rifkind, Wharton and Garrison, and currently, Sobo & Sobo.

26. Defendant Dr. Mario Fernandez is the principal of the New Paltz High School, located within Defendant New Paltz Central School District, and is the school from which I.R. has been excluded from enrolling.

27. Letitia James, in her capacity as the New York State Attorney General, shall be provided notice of this complaint contemporaneous with service of this complaint upon the Defendants.

FACTS

I. Plaintiff's Background and I.R.'s History

28. When Plaintiff began college, she was a pre-med major. During this time, she worked as a research assistant in the biology department at Cornell. She participated in a program that allowed her to shadow an infectious disease doctor, seeing AIDS patients, at Weil Cornell Medical in the early nineties. Plaintiff volunteered as an outreach educator while at Cornell to area youth in Ithaca teaching teens how to prevent AIDS transmission. Plaintiff also studied epidemiology at UCLA while an undergraduate.

A. I.R.'s History

29. Plaintiff gave birth to I.R., a health baby, who smiled for the first time at 1 month old. At 11 months old, I.R. said her first word and waved. As time progressed, I.R. suffered from various auto-immune dysfunctions and presented with allergy symptoms. Plaintiff immediately sought medical care for her daughter, beginning with several allergists. Plaintiff was advised to keep a food diary and apply creams and to do nothing that might further the already existing autoimmune dysregulation.

30. When I.R. was two years old, Plaintiff informed I.R.'s pediatrician (the same pediatrician Plaintiff herself had seen as a child) of concerning behaviors by I.R. including: lining

up objects repeatedly, failing to point to things, showing no interest in other children, and not responding to her name. In the 18 months that followed, Plaintiff consulted with leading institutions with regard to I.R.'s health including developmental pediatricians from Weil Cornell Medical and Bridget Taylor at Alpine Learning Group, among others.

31. I.R. was evaluated for early intervention and at two years and three months of age was found to be developmentally delayed with the skills of an eleven-month-old. I.R. did not make eye contact with others and when she spoke at all, it was rote and non-expressive language. I.R. was enrolled in early intervention and began to make progress in language skills. Plaintiff again turned to medical literature to research the best treatment for I.R. and what had once been ruled as pseudoscience was now the gold standard: Applied Behavioral Analysis ("**ABA**"). Its efficacy was supported by double blind placebo studies and so at 3 years and 8 months of age, Plaintiff entered I.R. into a full-time ABA program.

32. From the first day of her ABA program until the last day she left the building, I.R. thrived at her school as the curriculum taught her in a way that she was able to learn. I.R. would enthusiastically run into the building, pulling her teachers with her, each morning. I.R. learned to ask questions, acknowledge people in a room with her, and make eye contact with others. By four years old, I.R. learned to read and answered her first direct question. As time went on and I.R. was immersed in the ABA program, she learned to do amazing things including giving a presentation in class, winning a fundraising jump rope contest, attending birthday parties of peers and learning how to play Angry Birds like all of her friends. The professionals that educated I.R. during this time were invested in her individuality and never believed that I.R. was unable to learn.

B. I.R. is Suffering Without School

33. I.R. is suffering without being able to attend school. She is diagnosed with "other central nervous system dysfunction" and, at school, she was able to be with peers suffering from similar medical conditions as well as neurotypical peers. I.R. thrived at and enjoyed school, especially socializing with other children.

34. I.R. now has no contact with typical peers or those with similar conditions. Her prior placement was a classroom where there were up to five peers with similar medical conditions with three teachers, all within a typical school. This was meaningful in that she was able to interact with typical peers. I.R. would call out to people in the hallways and say hello or strike up a conversation. Now, instead, she spends 24/7 with her parents and without any peers.

35. I.R. also enjoyed interacting with her teachers and, overall, with the stimulating environment where she could engage with others. Instead of dedicated math and science teachers, I.R.'s parents now homeschool her while also working full-time professional jobs and taking care of a preschooler.

36. I.R. also previously participated on the school track team, an activity she sorely misses. She is now not able to run track or to learn to play a musical instrument, both of which she previously did and now misses.

37. I.R. is no longer able to participate in or experience school assemblies or concerts or gym classes or lunch time or attending special events.

38. I.R. no longer has the opportunity to interact with her bus drivers. It would be easy to underestimate what this added to her life but the bus driver and the aide on the bus were a large part of I.R.'s social life while attending school. I.R. developed friendships with them and this greatly and positively impacted her.

39. Now that I.R. has been excluded from school, her actual schooling hours are greatly reduced. There is, therefore, a lot of time I.R. spends on her phone, stimming, or watching videos. This is not productive time for I.R. She does not have the opportunity to be independent, make choices, or grow in an environment that is at times challenging yet also enriching.

40. I.R. is a social young lady who loves being with other people. Her least favorite thing is to be alone. Forcing her to be homeschooled deprives her of the right to a free public education but also deprives her of the social activity on which she thrives, as well as the emotional and academic opportunities that await in her school district.

41. Plaintiff observed numerous health conditions in I.R., over the past few years, that are indicative of a dysfunctional immune system. These symptoms include the inability to tan, shiners under I.R.'s eyes, pallor, eczema flare ups, and absence of any illnesses. In particular, I.R. has abnormally high elevated antibodies to various pathogens for which she has been vaccinated, such as her antibodies for pertussis and mumps, indicating an overly aggressive immune response to prior vaccination for these pathogens. Plaintiff has and continues to seek medical care to diagnose and treat I.R. for ongoing health conditions.

42. I.R.'s mother, based on her intimate knowledge of her daughter and her knowledge regarding Sanofi and GSK's tetanus, diphtheria and pertussis and polio products, declines to inject her again with these products; not only is there risk to her daughter, but there is no benefit to anyone else.

II. Cases of Pertussis, Tetanus, Diphtheria or Polio Did Not Decline After Vaccines for Pertussis, Tetanus or Diphtheria Were Required to Attend School Under NYS Law

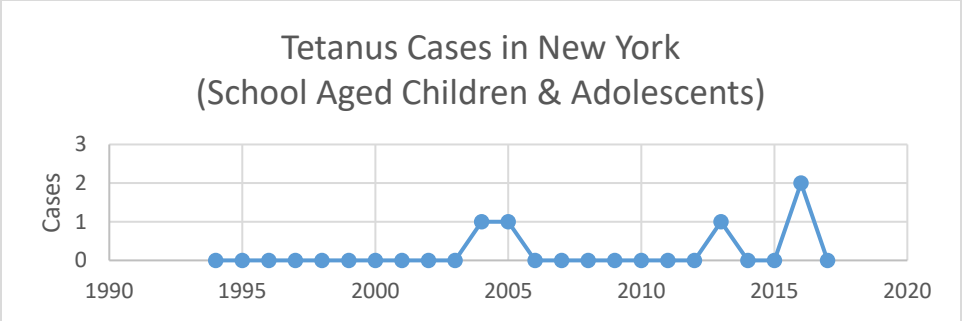
43. Vaccines are the only product that New York law requires a child to be administered in order to attend school. Nevertheless, the number of clinical cases (i.e., those

presenting symptoms) of tetanus, diphtheria, pertussis, and polio did not decline after New York State mandated vaccination for these infections.

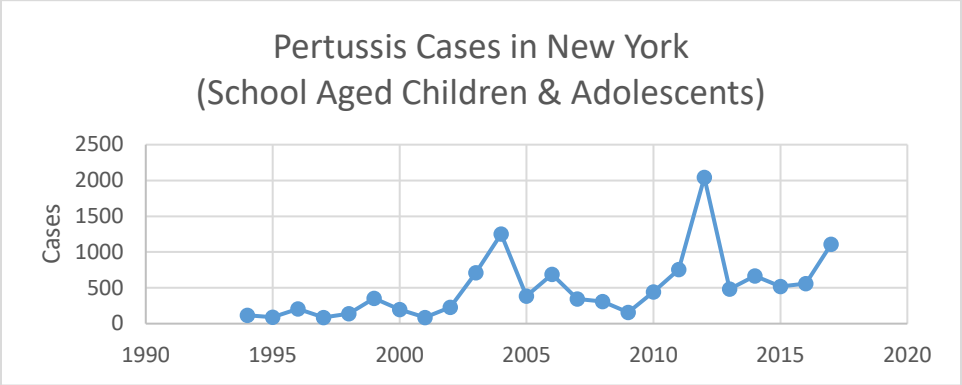
44. Students entering sixth grade for the 2007-2008 school year were the first children required under New York State law to receive a vaccine for tetanus or pertussis to attend school. (L 2006, ch 506.) For students below sixth grade, the first New York State law requiring them to receive a tetanus and pertussis vaccine to attend school only applied to children born after January 1, 2005. (L 2004, ch 207.) Hence, children entering kindergarten for the 2011-2012 school year were the first children below sixth grade required under New York State law to receive vaccines for tetanus and pertussis to attend school. (*Id*.)

45. According to data published by the NYSDOH, available from 1994 to 2017, the number of clinical cases of tetanus and pertussis did not decline after the legislature required vaccination for these infections. (https://www.health.ny.gov/statistics/diseases/communicable/).

46. The number of cases of tetanus remained effectively zero before and after the legislature required tetanus vaccine for sixth grade in 2007 and for kindergarten in 2011. Hence, not only is tetanus not communicable from student-to-student, but there was no practical reason for requiring this vaccine in New York State to attend school because tetanus was not a public health issue among school-aged children in the years prior to making the vaccination mandatory. Between 1994 and 2017, there were no cases of tetanus in each year among school-aged children in New York with the exception of one case in each of 2004, 2005 and 2013 and two cases in 2016 – that is 5 cases in 23 years. (https://www.health.ny.gov/statistics/diseases/communicable/). The following line graph reflects the number of cases of tetanus in New York among school-aged children between 1994 and 2017:



47. As for pertussis, the number of cases of pertussis actually increased after requiring this vaccine for sixth grade in 2007 and for kindergarten in 2011. Between 1994 and 2017, the annual incidence rate trend line for pertussis has increased, with approximately 100 to 2,000 cases of pertussis per year among school-aged children in New York, as seen in the following graph:



(https://www.health.ny.gov/statistics/diseases/communicable/)

48. With regard to diphtheria, New York State added vaccination for this bacteria as a requirement for school in 1971, and the law became effective in 1972. (L 1971, ch. 974.) According to the CDC, the incidence rate of diphtheria in New York in the years prior to and after this requirement has remained essentially zero. There was one case in all of New York in each year between 1968 and 1970, and no cases in 1971. After requiring the diphtheria vaccine for school, there were three cases in 1972, four cases in 1977, and one case in each of the following years: 1978, 1980, 1983, 1988, 1996, and 2012. Hence, the incidence rate of diphtheria among

New York's 18 million residents has remained essentially zero in the years directly prior to and after making this a required vaccine to attend school under New York State law.

49. Similarly, according to the CDC, there were zero cases of polio in New York in 1966, the year before the New York State legislature first enacted a requirement to receive the polio vaccine to attend school.

50. Consequently, the evidence is plain that making injection of these vaccines a legal requirement did not reduce the incidence of these infections in New York State.

III. Vaccines for Pertussis, Tetanus and Diphtheria and for Polio

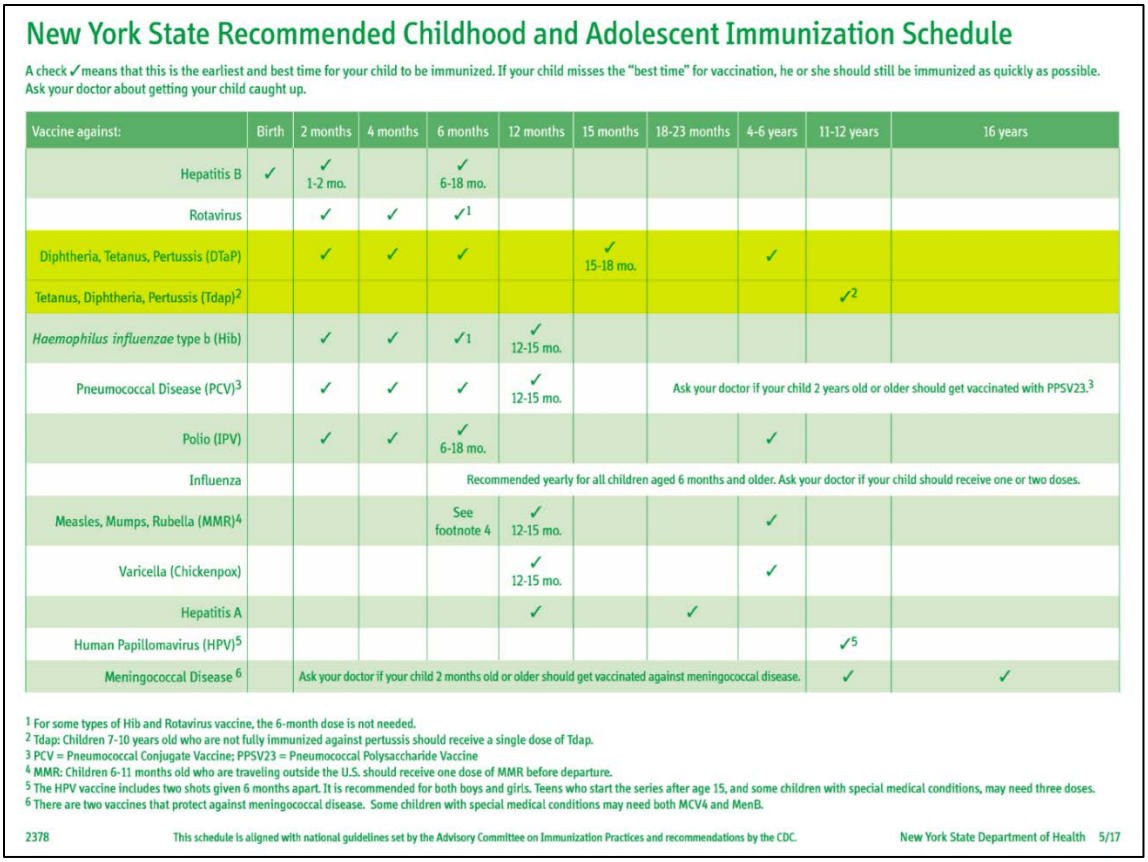
51. There is no standalone pertussis vaccine, tetanus vaccine, or diphtheria vaccine in the United States. Rather, they are available in the following formulations:

a. A tetanus, diphtheria and acellular pertussis vaccine ("**DTaP**"), licensed for children between 6-weeks and 6-years of age.

b. A tetanus, *reduced* diphtheria, and *reduced* acellular pertussis vaccine ("**Tdap**"), licensed for those 10 years of age and older.

c. A diphtheria and tetanus vaccine ("**DT**") licensed for children between 6-weeks and 6-years of age, and a tetanus and *reduced* diphtheria vaccine ("**Td**") licensed for those 7 years of age and older.

52. As reflected in the *New York State Recommended Childhood and Adolescent Immunization Schedule* (https://www.health.ny.gov/publications/2378.pdf), the pertussis, tetanus, and diphtheria vaccine requirements of PHL § 2164 and 10 NYCRR § 66-1.1(f) are met by administering DTaP at 2 months, 4 months, 6 months, 15 months, and 4 years of age, and a dose of Tdap at 11 years of age. The following is a copy of the New York State immunization schedule with the DTaP and Tdap requirements highlighted in yellow:



New York State Recommended Childhood and Adolescent Immunization Schedule

A check ✓ means that this is the earliest and best time for your child to be immunized. If your child misses the "best time" for vaccination, he or she should still be immunized as quickly as possible. Ask your doctor about getting your child caught up.

Vaccine against:	Birth	2 months	4 months	6 months	12 months	15 months	18-23 months	4-6 years	11-12 years	16 years
Hepatitis B	✓	✓ 1-2 mo.		✓ 6-18 mo.						
Rotavirus		✓	✓	✓[1]						
Diphtheria, Tetanus, Pertussis (DTaP)		✓	✓	✓		✓ 15-18 mo.		✓		
Tetanus, Diphtheria, Pertussis (Tdap)[2]									✓[2]	
Haemophilus influenzae type b (Hib)		✓	✓	✓[1]	✓ 12-15 mo.					
Pneumococcal Disease (PCV)[3]		✓	✓	✓	✓ 12-15 mo.		Ask your doctor if your child 2 years old or older should get vaccinated with PPSV23.[3]			
Polio (IPV)		✓	✓	✓ 6-18 mo.				✓		
Influenza				Recommended yearly for all children aged 6 months and older. Ask your doctor if your child should receive one or two doses.						
Measles, Mumps, Rubella (MMR)[4]				See footnote 4	✓ 12-15 mo.			✓		
Varicella (Chickenpox)					✓ 12-15 mo.			✓		
Hepatitis A					✓		✓			
Human Papillomavirus (HPV)[5]									✓[5]	
Meningococcal Disease[6]		Ask your doctor if your child 2 months old or older should get vaccinated against meningococcal disease.							✓	✓

[1] For some types of Hib and Rotavirus vaccine, the 6-month dose is not needed.
[2] Tdap: Children 7-10 years old who are not fully immunized against pertussis should receive a single dose of Tdap.
[3] PCV = Pneumococcal Conjugate Vaccine; PPSV23 = Pneumococcal Polysaccharide Vaccine
[4] MMR: Children 6-11 months old who are traveling outside the U.S. should receive one dose of MMR before departure.
[5] The HPV vaccine includes two shots given 6 months apart. It is recommended for both boys and girls. Teens who start the series after age 15, and some children with special medical conditions, may need three doses.
[6] There are two vaccines that protect against meningococcal disease. Some children with special medical conditions may need both MCV4 and MenB.

2378 This schedule is aligned with national guidelines set by the Advisory Committee on Immunization Practices and recommendations by the CDC. New York State Department of Health 5/17

53. Only a reduced dose of pertussis and diphtheria are used after age 7, and in the case of pertussis, it is only given once. This is because health authorities and pharmaceutical companies, prior to being granted financial immunity for vaccine injuries, could not ignore that the full dose results in an unacceptable level of adverse reactions in those over 6 years of age. Nevertheless, a full dose of pertussis and diphtheria is given at 2 months, 4 months, 6 months, 15 months and 4 years of age, when children are typically unable to properly express any adverse reactions they may be experiencing.

54. All pertussis, tetanus, and/or diphtheria-containing vaccines sold in the United States are manufactured and sold by either GSK or Sanofi. Their tetanus, diphtheria and pertussis containing vaccines are summarized in the following chart:

Type	Brand	Manufacturer	Year Licensed	Approved Ages
DT	generic	Sanofi	1978	6-weeks to 6-years
DTaP	Daptacel	Sanofi	1997	6-weeks to 6-years
DTaP	Infanrix	GSK	2002	6-weeks to 6-years
Td	Tenivac	Sanofi	2003	7 and older
Tdap	Boostrix	GSK	2005	10 and older
Tdap	Adacel	Sanofi	2005	10 and older

55. The only polio vaccine sold and used in the United States since 2000 is IPV manufactured and sold by Sanofi. *See* https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. This vaccine is *not* the polio vaccine created by Jonas Salk or Albert Sabin. IPV is something very different as Sanofi makes clear on the IPV's package insert. *Id.* For example, IPV, unlike these prior polio vaccines, grows the polio virus on different biological substrate, has a multi-fold more potent immunogenic content, uses microcarrier beads in production, and has different final ingredients. IPV was first licensed by Sanofi in 1990, eleven years after the last case of wild polio (as opposed to vaccine induced polio) in the United States.

56. GSK and Sanofi are estimated to have had over $2 billion in sales of their DTaP and Tdap products in 2018 alone. For example, GSK reported that sales of its Tdap product, Boostrix, amounted to $628,591,865 in 2018.

57. The Vaccines for Children Program ("**VFC**"), a federal government program created in 1993 and administered by the CDC, assures that GSK and Sanofi are paid for each dose of pertussis, tetanus and/or diphtheria-containing vaccine administered to any child in the United States who might not otherwise be able to pay. For the fiscal year 2019, the VFC program entered into a $1.633 billion contract with Sanofi and a $1.006 billion contract with GSK for the purchase of their vaccines. (https://www.fbo.gov/spg/HHS/CDCP/PGOA/75D301-19-R-67848/listing.html).

58. Despite the billions in revenue earned by Sanofi and GSK from sales of their DTaP/Tdap products to nearly all children in the United States, the extent of harm caused by these

products apparently still require GSK and Sanofi to have financial immunity under federal law for these harms.

IV. Overview of the Government Program Regarding Vaccine Safety of DTaP, Tdap, and IPV

59. Vaccines are the only product where the government agency responsible for ensuring their safety is also responsible for promoting the product and for defending the product in court against any claim it caused harm.

A. The National Childhood Vaccine Injury Act of 1986

60. New York State and the NYSDOH rely on the United States Department of Health & Human Services ("**HHS**") and the Centers for Disease Control & Prevention ("**CDC**") to claim that vaccines are safe. This is because the 1986 Act made HHS, and its agencies, including the CDC, solely responsible for vaccine safety.

61. The genesis of how HHS became singularly responsible for vaccine safety begins in the early 1980's when the liability to pharmaceutical companies from harms caused by their vaccine products far exceeded the revenue from their vaccine products. As explained by the Institute of Medicine, by 1986 the "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines." There were only three routine vaccines at that time and only one manufacturer remained for each of these vaccines.

62. One of these three vaccines was a tetanus, diphtheria and pertussis-containing vaccine. The harm it caused was many factors greater than the substantial revenue it generated. As explained above, the U.S. Supreme court found that "by the mid-1980's … the remaining manufacturer [of DTP vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011).

63. Instead of allowing market forces to obligate these companies to make a safer product, Congress did the opposite. Congress passed the National Childhood Vaccine Injury Act of 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34, which virtually eliminated financial liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 ("No person may bring a civil action for damages in the amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death."); *Wyeth LLC*, 562 U.S. at 243 ("we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").[1]

64. By granting pharmaceutical companies immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the financial incentive for pharmaceutical companies to assure vaccine safety because they were no longer accountable for harms caused by their vaccine products. Recognizing the unprecedented elimination of this market force, Congress enacted the "Mandate for Safer Childhood Vaccines" as part of the 1986 act, which made HHS directly responsible for virtually every aspect of assuring vaccine safety (the "**Mandate**"). 42 U.S.C. § 300aa-27.

65. The Mandate underpins all vaccine safety in this country and has three simple parts:

> (a) **General Rule.** … [T]he Secretary shall—(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions …, and (2) make or assure improvements in … the licensing, … testing, labeling, warning,

[1] The prices of tetanus, diphtheria and pertussis containing vaccines have rapidly increased since 1986 despite the fact that pharmaceutical companies have immunity from financial liability for vaccine injuries, they sell these products to a captive market of 78 million children required to take them under penalty of expulsion from school, and HHS/CDC markets these products to the public using taxpayer money. For example, the prices for the Td (tetanus and diphtheria) has increased 4,573% between 1987 ($.065) and 2006 ($29.73).

> … field surveillance, [and] adverse reaction reporting … of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
>
> (b) **Task Force.** The Secretary shall establish a task force on safer childhood vaccines which … shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).
>
> (c) **Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the … House of Representatives and the … Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

66. Part "a" of the Mandate requires the Secretary of HHS to assure and improve every aspect of vaccine safety. Part "b" creates the Task Force on Safer Childhood Vaccines (the "**Task Force**") to make recommendations to the Secretary of HHS on how to improve vaccine safety. Part "c" requires the Secretary of HHS to submit a report to Congress every two years, starting in 1989, detailing the improvements made to vaccine safety in the preceding two years.

67. These safeguards to assure vaccine safety are only effective if HHS implements them. Unfortunately, the Task Force required by part "b" of the Mandate was disbanded in 1998; and, as HHS conceded in federal court, it has not prepared or filed a single biennial vaccine safety report for Congress as required by part "c" of the Mandate. *Informed Consent Action Network v. United States Department of Health and Human Services*, 18-cv-03215-JMF, (Doc # 18) (S.D.N.Y, July 9, 2018). HHS has similarly failed to fulfill the far more difficult work required by part "a" of the Mandate to actually assure and improve vaccine safety, which is apparent from a recent letter exchange with HHS regarding vaccine safety. *See* https://www.icandecide.org/wp-content/uploads/2019/08/ICAN-Reply-1.pdf.

68. There are other parts of the 1986 Act that HHS has vigorously fulfilled, specifically its obligations to (i) increase vaccine uptake and (ii) defend against legal claims that a vaccine caused an injury.

69. As for vaccine uptake, HHS spends over $5 billion annually promoting and purchasing vaccines. As for defending claims of vaccine injury in court, the 1986 Act established the Vaccine Injury Compensation Program ("**Vaccine Court**"), part of the U.S. Court of Federal Claims. Congress intended the Vaccine Court to serve as a way to compensate people injured by vaccines. (https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters). If an individual is injured by a vaccine, he or she must bring a claim in the Vaccine Court. HHS is the respondent in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury. 42 U.S.C. § 300aa-12 ("In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary [of HHS] shall be named as the respondent.") Hence, HHS, while responsible for vaccine safety, is simultaneously responsible for the conflicting duties of promoting vaccines and for defending against claims of vaccine injuries.

70. In Vaccine Court, HHS is represented by the formidable resources of the U.S. Department of Justice ("**DOJ**") and vigorously defends against any claim that a vaccine causes injury. Congressional reports have found that "DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," and "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims."

71. The 1986 Act created a Vaccine Injury Table (the "**Table**") which Congress intended the Vaccine Court to use to quickly compensate certain common vaccine injuries. 42 U.S.C. § 300aa-12. For injury types appearing on the Table, the burden was on the HHS to prove the vaccine

is not the cause of the injury, on the other hand, if the injury was not on the table, the injured person carried the burden to prove causation. 42 U.S.C. § 300aa-13. After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled, just as Congress had intended. *Stevens v. Secretary of HHS*, No. 99-594V (Office of Special Masters 2001). However, in the 1990s, HHS amended the Table such that now 98% of new claims are off-Table. *See* http://www.gao.gov/assets/670/667136.pdf. As a result, today's parents of injured children must prove that the vaccine was the cause in almost all cases.

72. The burden on the injured person to prove causation is far greater than would exist in a typical court because of the circumstances presented in Vaccine Court. First, there is no discovery as of right in Vaccine Court and discovery is only granted "in rare and exceptional cases." Second, most babies and toddlers cannot express their symptoms, other than incessant and uncontrollable screaming (which is fairly common following vaccination), therefore pinpointing the exact injury, symptoms, and when it occurred is often difficult. Third, medical experts are typically worried about testifying in support of a claim that a vaccine caused an injury due to the public stigma surrounding such claims, hence medical professionals rarely agree to serve as experts for petitioners in Vaccine Court. Fourth, as explained by the Federal Circuit, medical science is "a field bereft of complete and direct proof of how vaccines affect the human body." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

73. Assuming a parent of a vaccine injured child even knows about Vaccine Court and contacts an attorney within the strict three-year statute of limitations, most claims are never asserted because of the futility of proving causation. Despite these hurdles, since 2000, HHS has paid over $500,000,000 for injuries caused by tetanus, diphtheria and pertussis containing vaccines

even though there is a statutory cap of $250,000 for death, and for pain and suffering. 42 U.S.C.A. § 300aa-15(a)(2), (4).

74. The following are some of the disorders and injuries following vaccination for tetanus, diphtheria and/or pertussis for which compensation was paid in Vaccine Court since 2000:

> abscess, acute disseminated encephalomyelitis (ADEM), acute liver failure, adhesive capsulitis, aggravation of pre-existing encephalopathy, agoraphobia, anaphylactic shock, anaphylaxis, antisynthetase syndrome, angiomatoid fibrous histiocytoma, anxiety, aplastic anemia, arm injury, arthritis, ataxia, autism, autoimmune hep type 2, autoimmune hemolytic anemia, behavioral issues, bell's palsy, benign tumor, bilateral peripheral neuropathy, bilateral shoulder pain, bilateral symmetric diaphragmatic palsy, blindness, brachial neuritis, brachial plexopathy, brachial plexus neuritis, cardiac injury, celiac disease, cellulitis, cerebellitis, cerebellar ataxia, cerebrovascular accident, chest pain, choreiform movement disorder, chronic fatigue, chronic gastrointestinal issues, chronic arthritis, chronic inflammatory demyelinating polyneuropathy (CIDP), chronic urticarial, demyelinating disease of central nervous system, demyelinating polyradiculoneuropathy, chronic pain, complex regional pain syndrome, death, deltoid bursitis, demyelinating condition, demyelinating sensorimotor polyneuropathy, dermatomyositis, dravet syndrome, developmental delay, devic's disease, eczema, encephalitis, encephalopathy, epilepsy, Epstein-Barr virus, erythema multiforme major, Evans Syndrome, exacerbation of existing cardiomyopathy, expressive language delay, fatigue, fibromyalgia, frozen shoulder, gastrointestinal symptoms, gastroparesis, GM1 gangliosidosis, guillain-barre syndrome (GBS), headaches, hemophagocytic lymphohistiocytosis (HLH), hodgkin's lymphoma, hypereosinophilia, hypersensitivity, hypotensive-hyporesponsive shock collapse (HHE), hypoproteinemia, hypotonia, immobile flaccid legs, immune issues, immune thrombocytopenia purpa, increased risk of cancer, infantile spasms, inflammatory arthritis, joint pain, juvenile dermatomyositis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis (JRA), kawasaki disease, keloid scarring, leukocytoclastic vasculitis (LCV), leukodystrophy, latent herpes simplex virus infection, lichen planus, lipomas, long thoracic nerve palsy, lupus (SLE), lymphangitis, lymphomatoid granulomatosis, macrophagic myofasciitis, meningoencephalitis, metal toxicity, mixed connective tissue disease (MCTD),

monoplegia, multi organ failure, multiple sclerosis, muscle spasms, myalgias, myelitis, necrotizing pancreatitis, nerve damage, neurological injury, neuromyelitis optica (NMO), neuropathic arm pain, neuropathy, nodular fasciitis, opsoclonus-myoclonus syndrome (OMS), ocular visual disturbance, optic neuritis, panic, overlap syndrome, panuveitis, panniculitis, parsonage turner syndrome, pemphigus vulgaris, peripheral neuropathy, permanent spastic tetraparesis, polyarthralgia, progressive encephalopathy, psoriatic arthritis, pulmonary edema, SIDS, radial nerve damage, rash, reactive inflammatory arthritis, reflex sympathetic dystrophy, residual seizure disorder (RSD), retro seizures, rhabdomyolysis, rheumatoid arthritis, rheumatologic injuries, scaring, scn1a, seizures, seizure disorder, sensory neuropathy, sensory polyneuropathy, serum sickness, sirva, small fiber neuropathy, shoulder pain, splenic rupture, abscesses, strep infection, stroke, suprascapular neuropathy, syncope, synovitis, tendonitis, tendinopathy, toxic epidermal necrolysis (TEN), toxic shock syndrome, transverse myelitis (TM), thrombocytopenic purpa, tics, tremors, undifferentiated connective tissue disease (UCTD), urinary incontinence, uticarial andgiodema, uveitis, vasculitis, vestibular neuronitis

75. The following are some of the disorders and injuries following vaccination with IPV for which compensation was paid in Vaccine Court:

Abscess, acute disseminated encephalomyelitis, acute renal failure, anaphylactic reaction, anaphylactic shock, anaphylaxis, angiomatoid fibrous histiocytoma, aplastic anemia, ataxia, autism, autoimmune hemolytic anemia, brachial neuritis, cerebellar ataxia, cerebellitis, cerebrovascular event, chronic inflammatory demyelinating polyneuropathy, chronic urticaria, choreiform movement disorder, Coombs' Positive hemolytic anemia, choreiform movement disorder, cryptogenic infantile spasms, death, dermatomyositis, developmental delay, Devic's disease, eczema, encephalitis, encephalopathy, encephalopathy epilepsy, Evan's Syndrome, expressive language delay, febrile status epilepticus, flaccid legs, Guillain-barre syndrome, hemophagocytic lymphohistiocytosis, hypereosinophilia, idiopathic thrombocytopenia purpa, immobile, infantile spasms, intussusception, juvenile dermatomyositis, leukodystrophy, macrophagic myofascitis, monoplegia, morphea, neutropenia, neurologic impairment, optic neuritis, pancytopenia, Parsonage Turner Syndrome, peripheral neuropathy, permanent Spastic tetraparesis, post-traumatic stress disorder, reactive inflammatory

> arthritis, residual seizure disorder, right femoral nerve damage, scarring, seizures, SIDS, significant aggravation of multiple sclerosis, shoulder injury related to vaccine administration (SIRVA), splenic rupture, sterile abscesses, strep infection, stroke, synovitis, thrombocytopenia, thrombocytopenic purpa, tics, torticollis, transverse myelitis, urinary incontinence, weakness.

76. If HHS publishes any study supporting that a tetanus, diphtheria, pertussis or IPV vaccine causes a harm, or makes any such statement, that study or statement will be used as evidence against HHS in Vaccine Court. For example, if a single study published by HHS supports that even 1 in 5 cases of a common autoimmune or atopic disease (such as asthma) are caused, directly or indirectly, by DTaP vaccines (or the aluminum adjuvant therein), the study would be used as evidence against HHS in Vaccine Court and could result in hundreds of billions of dollars in liability. This greatly limits HHS's incentive to publish safety studies that may support that DTaP/Tdap or IPV causes a given harm.

B. Clinical Trials Relied Upon by the FDA to License DTaP, Tdap, and IPV

77. Given HHS's duty to assure vaccine safety for GSK and Sanofi's liability-free DTaP/Tdap and IPV products, and that these products are given to healthy children, it would be expected that the clinical trial relied upon to license these products would be extremely robust. That at the least, they would be similar to the clinical trials typically performed to license drugs. Unfortunately, that is not the case.

78. Drugs licensed by the FDA undergo multi-year double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving a placebo. A "placebo" is "[a] substance or treatment that has no effect on human beings." (https://www.cdc.gov/vaccines/terms/glossary.html). Common examples of a placebo are a saline injection or sugar pill. The reason that drugs are first evaluated in a clinical trial against a control group receiving a placebo, prior to

being released to the public, is to assess the drug's safety and effectiveness. (https://www.nia.nih.gov/health/why-are-placebos-important).

79. For example, Enbrel's pre-licensure trial followed subjects up to 80 months and controls received a saline injection. (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf). Lipitor's pre-licensure trial lasted a median of 4.8 years and controls received a sugar pill. (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf). Botox's pre-licensure trial lasted a median of 51 weeks and controls received a saline injection. (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf). The weight loss drug Belviq, only indicated for adult use, was safety tested in a 2-year placebo-controlled trial before being licensed. (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf).

80. However, for each pertussis, tetanus, diphtheria, and IPV containing vaccine given to babies and toddlers, the clinical trials relied upon to assess its safety prior to licensure did *not* have a placebo-control group. Moreover, the safety review period in these clinical trials were typically around one month after injection with, sometimes, a follow-up phone call at six months. *Id*.

81. For example, GSK's DTaP vaccine, Infanrix, was licensed based on a clinical trial in which a DTP vaccine (not a placebo) was used as the control and had a safety review period of only around 30 days after injection. (https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf). Without a placebo-controlled clinical trial, the actual safety profile of this and every other DTaP/Tdap vaccine cannot be assessed even for the limited duration that its safety was reviewed. And, even assuming placebo controls were used, tracking safety for even 6 months – let alone only 30 days – after injecting a baby or toddler will not reveal if the

vaccine caused autoimmune, neurological or developmental disorders that are likely to only be apparent or diagnosed after the child is a few years of age, or the autoimmune, neurological or developmental disorders that arise over a longer time period.

82. As another example, GSK's package insert for Boostrix, its Tdap product, provides that "Serious adverse events were reported to occur by 4.2% . . . of subjects who received BOOSTRIX." (https://www.fda.gov/media/124002/download). But because there is no placebo control group, GSK and their paid researchers are left to determine if each reported adverse event in their trial is related to the vaccine. If a placebo control group were used, then there would be no need for a case-by-case determination by GSK and its paid researchers regarding whether each reported adverse reaction was related to the vaccine under review. It is only because of the lack of placebo-controlled trials that there is a need to rely on the "judgment" of pharmaceutical company paid researchers to decide if the adverse event is related to the vaccine.

83. IPV, the only polio vaccine used in the United States, was licensed in 1990 by Sanofi based on a clinical trial that had a safety review period of 3 days after injection. https://www.fda.gov/media/75695/download. As noted above, this is not the polio vaccine created by Jonas Salk or Albert Sabin – this is something very different as Sanofi makes clear on the IPV's package insert.

84. With all non-vaccine drugs, the pharmaceutical industry remains accountable for safety and liable in civil court for injuries caused by the drugs they put on the market. Hence, during pre-licensure clinical trials for drugs, pharmaceutical companies have a financial incentive to their shareholders to ascertain each drug's safety profile – to determine if its liability exposure exceeds its likely revenue stream – otherwise, after licensure the company could face losses that exceed the drug's expected sales. This is likely why pharmaceutical companies conduct long-

term, placebo-controlled trials before seeking licensure for even short-acting, minor or cosmetic prescription or over-the-counter drugs. And even then, many drugs end up causing more harm than they prevent and are removed from the market through litigation.

85. In contrast, pharmaceutical companies do not have liability for injuries caused by most of their vaccine products but yet their DTaP, Tdap, and IPV products were each licensed based on a clinical trial without any placebo control and at most, a few months of safety review after injection. This defective, minimal pre-licensure review of DTaP/Tdap and IPV products is, however, in line with their fiduciary duty to their shareholders since these companies have a financial incentive to get them licensed as fast as possible with as little review of their safety profile as possible.

86. DTaP/Tdap and IPV vaccines generate billions of dollars in revenue annually. If it turns out that the vaccine causes serious harm, and a parent can prove it in Vaccine Court (over the defense of HHS and DOJ), the claim is paid by the Federal Government using funds obtained from an excise tax collected from vaccine consumers. It is not paid by GSK or Sanofi. Thus, GSK and Sanofi have a financial disincentive to identify safety issues that would prevent licensure and little incentive to identify or correct safety issues with these vaccines after licensure.

87. Despite the 1986 Act making HHS responsible for vaccine safety, it has failed to fulfill this duty, with regard to these vaccines, by not requiring long-term, placebo-controlled clinical trials of these products prior to licensure. Without such trials, the actual safety profiles of these products were not determined before licensure. And after licensure -- because of its dual role as the defender in Vaccine Court – HHS becomes conflicted from publishing research that reveals that one or more of these products it licensed and recommends causes significant harm to more than a few children.

88. Indeed, identifying and admitting, after licensure, that this product causes or is even likely to cause certain serious harm would eliminate HHS's ability to defend itself against claims alleging such harm in Vaccine Court, which could amount to billions or trillions of dollars in financial liability. If this were to happen, it would also tarnish HHS's reputation and reduce the public's trust in HHS because, unlike drugs, HHS spends billions of dollars annually purchasing, distributing and vigorously promoting these products. This creates a serious conflict of interest within HHS that prevents it from unbiasedly evaluating post-licensure reports of adverse events. It is therefore critical for HHS to have a clear and robust picture of the actual safety profile of these products *before* they are recommended and promoted by HHS to the public. But this never occurred for any DTaP/Tdap or IPV vaccine prior to licensure and hence the actual safety profile of these products was not known prior to licensure.

89. In theory, the above safety should be at least partially filled by the FDA and CDC at the time of licensure, because at that time those agencies (both part of HHS) should have an incentive to only license vaccines that are safe and will not cause issues. Nevertheless, Congress has repeatedly found that the members of the FDA and CDC committees, serving during the period most of the currently licensed and recommended TDaP/Tdap and IPV vaccines were approved, had serious conflicts of interests because "[t]he overwhelming majority of members [of the FDA's vaccine licensing committee], both voting members and consultants, have substantial ties to the pharmaceutical industry" and those pharmaceutical companies have an incentive to approve highly profitable vaccines as quickly as possible. https://bit.ly/2T6ChPX; *Id.* (The process for recommending vaccines by the CDC reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed.") *See also* https://oig.hhs.gov/oei/reports/

oei-04-07-00260.pdf (HHS Office of Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for [advisory panel members]").

C. Post-Licensure Safety Studies of DTaP, Tdap, and IPV

90. Beyond the conflicting financial, statutory and reputational interests, there are additional problems with post-licensure testing of these vaccines. After licensure, conducting a placebo-controlled clinical trial is considered unethical. Without the ability to conduct a proper placebo-controlled clinical trial, researchers are typically left with population studies (epidemiological studies). These population studies can typically never prove or disprove causation and are subject to biases (a.k.a., cofounders), and therefore, are considered the weakest form of proof. Nonetheless, the limited vaccine safety studies conducted after licensure of a vaccine are almost all retrospective epidemiological studies of one claimed injury for one vaccine.

91. Having to "work backward" to try and determine safety in this snail-paced-and-handicapped manner would not be necessary if a properly powered long-term placebo-controlled clinical study were performed before licensure because such a trial could compare the total health outcomes between a group receiving the vaccine and the group receiving a placebo. In this way, society would have data that clearly reflected the rate of autoimmune issues, immune dysfunction, neurological disorder or other chronic health issues between those receiving the vaccine and those receiving a placebo. This never happened before licensure of any DTaP/Tdap or IPV vaccine product, and because of "ethical" constraints, it cannot happen after licensure (even though it never happened before licensure).

92. Nevertheless, after licensure and use by the public, federal regulation requires that the manufacturer – based on the product's post-licensure experience – include in the package insert for each vaccine "*only* those adverse events for which there is some basis to believe there is a *causal*

relationship between the drug and the occurrence of the adverse event." 21 C.F.R. 201.57 (emphasis added). Under this regulation "*only*" those adverse events where a "*causal*" relationship is believed to exist are to be included in the insert. For example, inserts DTaP/Tdap vaccines include over one hundred serious immune, neurological and other chronic conditions that Sanofi or GSK had a basis to believe are caused by their products based their experience with these products after licensure:

> abnormal liver function tests, allergic reactions (such as erythematous rash, maculopapular rash, urticaria and pruritus), anaphylactic reaction (including bronchospasm, angioedema edema, face edema, swelling face, pruritus, rash generalized), anaphylactoid reaction, anaphylaxis, angioedema, apnea, arthralgia, arthus hypersensitivity, back pain, brachial neuritis, bronchitis, bulging fontanelle, cellulitis, collapse or shock-like state (hypotonic153 hyporesponsive episode), convulsions (with or without fever), cyanosis, decreased appetite, depressed level of consciousness, diarrhea, dizziness, dyspnea, ear pain, edema, edema peripheral, encephalitis, encephalopathy, erythema, erythema multiforme, exanthem, extensive limb swelling from the injection site beyond one or both joints, extensive swelling of injected limb (including swelling that involves adjacent joints), face edema, facial palsy, fatigue, febrile convulsion, febrile seizure, grand mal convulsion, Guillain-Barré syndrome, Henoch-Schönlein purpura, HHE, hypersensitivity and allergic reactions (such as rash, urticaria, 121 dyspnea), hypersensitivity reaction (angioedema, edema, rash, hypotension), hypoesthesia, hyporesponsiveness, hypotonia, hypotonic-hyporesponsive episode (i.e., sudden onset of hypotonia, hyporesponsiveness, and pallor or cyanosis),induration, inflammation, injection site issues (including abscess, bruising, cellulitis, induration, inflammation, mass, nodule, lump, pain, pruritus, edema, vesicles), insomnia, large injection site reactions (>50 mm) including limb swelling which may extend from the injection site beyond one or both joints, lethargy, limb pain and swelling, listlessness, loss of consciousness, lymphadenitis, lymphadenopathy, macular, maculopapular rash, malaise, meningitis, muscle spasm, musculoskeletal stiffness or pain, myalgia, myelitis, myocarditis, myositis, nausea, nervousness, pain, pain in extremities, pallor, paresthesia, partial seizures, peripheral oedema, petechiae, pruritus, pyrexia, restlessness, rhinitis, screaming, seizure, shock, somnolence, sterile abscess, Sudden Infant Death Syndrome, sudden onset of hypotonia, swelling face,

syncope, tenderness, thrombocytopenia, thrombocytopenia urticaria, unusual crying, urticaria, vasovagal responses to injection

The foregoing list reflects conditions with relatively immediate onset following vaccination. Long-term adverse reactions are not likely to be deemed by GSK or Sanofi to be causally related to their products without a properly controlled longer term safety study -- but as noted this is not done before or after licensure of these products.

93. Instead of these serious adverse event reports resulting in a call to action by the CDC to conduct long-term studies that could reasonably establish if these adverse events are causally related to these products, the response has been the opposite. The CDC publicly hides behind the claim that no causation has been proven. But as the CDC is well aware, *without* a placebo control trial, cause and effect is very difficult and often impossible to establish. As explained by the CDC's own guidance material: "establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible," rather, researchers need "to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons"; the entire advantage of a randomized placebo-controlled trial "is the ability to demonstrate causality i.e., cause-effect relationship"; and the Vaccine Adverse Events Reporting System (VAERS) is unable "to determine causation" because "there is a lack of an unvaccinated group for comparison in VAERS." Therefore, no matter how many or what type of vaccine injuries are reported, the CDC along with GSK and Sanofi can and do hide behind the claim that "a cause and effect relationship with the vaccine has not been established."

94. This is what makes the lack of a placebo in clinical pre-licensure trials for DTaP, Tdap, and IPV all the more troubling. Had such a comparison been conducted prior to licensure, the CDC would likely not need to resort to stating that no cause and effect has been established when a parent complains this product injured their child. This assertion is not assuring because it

also means a causal relationship has not been disproven. A parent whose child suffered a serious condition after a DTaP/Tdap or IPV vaccine and who is waiting for a study to support or disprove a causal relationship between these products and their child's injury will likely be waiting forever. This is because a placebo-controlled trial is not undertaken prior to licensure and is considered unethical to undertake after licensure.

95. The lack of sufficient safety studies for DTaP/Tdap and the IPV vaccines is evident from reports by the Institute of Medicine ("**IOM**"), which is part of the National Academy of Sciences and recently changed its name to the National Academy of Medicine. In 1991 and 1994, at HHS's request and in compliance with a congressional mandate in the 1986 Act, the IOM appointed committees to examine the scientific literature and other evidence that could either prove or disprove a causal link between serious health problems commonly reported to result from certain vaccines. The first report, *Adverse Effects of Pertussis and Rubella Vaccines*, was published in 1991, and the second report, *Adverse Effects Associated with Childhood Vaccines*, was published in 1994.

96. In its report from 1991, the IOM examined 18 commonly reported serious injuries following pertussis containing vaccines. (https://www.nap.edu/read/1815/chapter/2#7). The IOM located sufficient science to support a causal connection between pertussis vaccines and four of these injuries: acute encephalopathy, anaphylaxis, protracted inconsolable crying, and shock and unusual shock-like state. The IOM, however, found the scientific literature was insufficient to conclude whether or not the pertussis vaccine can cause 10 of these commonly reported serious injuries:

> aseptic meningitis, autism, chronic neurologic damage, erythema multiforme, hemolytic anemia, Guillain-Barre syndrome, juvenile diabetes, learning disabilities and attention-deficit disorder, peripheral mononeuropathy, thrombocytopenia

https://www.nap.edu/read/1815/chapter/2#7

97. The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines." (https://www.nap.edu/read/1815/chapter/2#8). It therefore cautioned that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped." (https://www.nap.edu/read/1815/chapter/9).

98. In its report from 1994, the IOM examined 11 commonly reported serious injuries following tetanus and diphtheria-containing vaccines. (https://www.nap.edu/read/2138/chapter/2#12). The IOM located sufficient science to support a causal connection between these vaccines and three of these injuries: anaphylaxis, Guillain-Barre syndrome and brachial neuritis. The IOM, however, found the scientific literature was insufficient to conclude whether or not these vaccines can cause five of these commonly reported serious injuries:

> arthritis, demyelinating diseases of the central nervous system, erythema multiforme, mononeuropathy, residual seizure disorder

https://www.nap.edu/read/2138/chapter/2#12. This report also examined 5 commonly reported serious injuries following IPV vaccine and for all of them found the scientific literature was insufficient to conclude whether or not IPV causes these conditions: transverse myelitis, thrombocytopenia, anaphylaxis, Guillain-Barre syndrome, and death. *Id.*

99. As in 1991, this IOM Report again stated, "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern." (https://www.nap.edu/read/2138/chapter/12)

100. In 2012, more than fifteen years after the IOM Reports in 1991 and 1994, HHS paid the IOM to conduct another assessment regarding vaccine safety. (https://www.nap.edu/read/13164/chapter/2#2). This third IOM Report examined 27 commonly reported serious injuries following tetanus, diphtheria or pertussis containing vaccines. The IOM located science which convincingly supports a causal relationship with one of these injuries and which rejects a causal relationship with one of these injuries. For the remaining 25 injuries, the IOM found the scientific literature was insufficient to conclude whether or not these are caused by tetanus, diphtheria or pertussis containing vaccines:

> acute disseminated encephalomyelitis, ataxia, autism, bell's palsy, chronic inflammatory demyelinating polyneuropathy, chronic urticaria, encephalitis, encephalopathy, Guillain-Barre syndrome, infantile spasms, multiple sclerosis, myocarditis optic neuritis, opsoclonus myoclonus syndrome, seizures, scrum sickness, transverse myelitis

(https://www.nap.edu/read/13164/chapter/2#2). Thus, out of the 27 most common serious injuries claimed to have been caused by tetanus, diphtheria and/or pertussis containing vaccines, the IOM found that for over 92% of those the science simply had not been performed to determine if there is a causal relationship between this vaccine and the commonly claimed serious injury.

101. As for which children are likely to be harmed by a vaccine, the IOM has explained that "most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility," yet HHS and CDC have failed to conduct studies to identify children susceptible to vaccine harms (while at the same time recommending DTaP/Tdap and IPV for all children). *See* https://www.icandecide.org/wp-content/uploads/2019/08/ICAN-Reply-1.pdf § V.

102. In 1994, the IOM stated that "[t]he committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not" and urged that

"research should be encouraged to elucidate the factors that put certain people at risk." https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9

103. Yet, 17 years later, in 2012, the IOM acknowledged this research had still not been done:

> Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact…
>
> Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine… much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.

https://www.nap.edu/read/13164/chapter/5#82

104. In 2013, the IOM again found that while "most children who experience an adverse reaction to immunization have preexisting susceptibility" it "found that evidence assessing outcomes in subpopulations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty." https://www.nap.edu/read/13563/chapter/9#130

105. Amazingly, while short term adverse events are common after vaccination with DTaP, Tdap and IPV, the IOM acknowledges that science does not even yet know "if there is a relationship between short-term adverse events following vaccination and long-term health issues." (https://www.nap.edu/read/13563/chapter/5#46). HHS and CDC have nonetheless failed to conduct studies to determine if there is a causal relationship between vaccination and long-term

health issues even despite the CDC admitting that "because the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events."

106. As for the prevalence of vaccine harm from tetanus, diphtheria, and/or pertussis containing vaccines, the CDC's Vaccine Adverse Events Reporting System ("**VAERS**") is a system to which doctors and patients may *voluntarily* report adverse vaccine events. (According to HHS, 83% of VAERS reports come from vaccine manufacturers, health care providers and state immunization programs, and 7% come from vaccine recipients or their guardians.) Since 2000, VAERS has received over 150,000 reports of vaccine injury from tetanus, diphtheria, pertussis and/ or IPV containing vaccines, including 2,445 deaths, 2,761 permanent disabilities, 18,247 hospitalizations, and 43,909 emergency room visits. An HHS-funded three-year review by Harvard Medical School of 715,000 patients stated that "fewer than 1% of vaccine adverse events are reported" to VAERS. https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf[2] This could mean there are a hundredfold more adverse vaccine events than are reported to VAERS. The CDC has nonetheless refused to mandate or automate VAERS reporting. *See* https://www.icandecide.org/wp-content/uploads/2019/08/ICAN-Reply-1.pdf at § III.

107. A true epidemic in the United States is the fact that 1 in 2 children have an autoimmune, developmental, neurological, or other chronic disorder. These conditions have sharply risen in lockstep with the increases in the CDC's recommended vaccine schedule. That

[2] *See also* Congressional report stating that: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."; https://www.ncbi.nlm.nih.gov/pubmed/22531966 ("a confidential study conducted by Connaught Laboratories, a vaccine manufacturer, indicated that 'a fifty-fold underreporting of adverse events' is likely.")

schedule has risen from 7 injections of just 2 vaccines in 1986 to the current total of 50 injections of 12 different vaccines. *Compare* https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg *with* https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf. This correlation should result in studies that compare health outcomes of vaccinated and unvaccinated children in order to rule out vaccines, including vaccines for tetanus, diphtheria, pertussis and IPV containing vaccines, as a contributing cause. Yet, despite decades of demands by the public, the CDC has never published a study comparing health outcomes between vaccinated and unvaccinated children. Not even retrospective studies looking at prior data which would pose no ethical dilemma.

108. The limited studies that have conducted such a comparison have found troubling results. For example, the seminal natural experiment comparing death rates between babies receiving diphtheria, tetanus and pertussis vaccine and those receiving no vaccines during the first six months of life found that the vaccinated babies died at ten times the rate. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/.) As another example, a recent pilot study from the School of Public Health at Jackson State University conducted the first ever comparison of vaccinated and unvaccinated children in the United States and found that vaccinated children in this study had an increased risk of 290% for eczema, 390% for allergies, 420% for ADHD, 420% for autism, and 520% for learning disabilities. (https://www.oatext.com/pdf/JTS-3-186.pdf). Nonetheless, HHS and CDC refuse to publish any studies comparing the health outcomes between vaccinated and unvaccinated children. When vaccine makers are generating over $33 billion in vaccine revenue annually and the CDC is spending over $5 billion annually to promote and purchase vaccines, there is no justification for not publishing at least a retrospective vaccinated versus unvaccinated study.

V. Medical Establishment's Religious Beliefs Regarding DTaP, Tdap, and IPV

109. Despite the foregoing, legislative representatives and health officials in New York respond to any concern regarding any vaccine product with the mantra that they "believe in science" and that the science is settled with regard to the safety and efficacy of pertussis, tetanus, diphtheria and IPV containing vaccines. This mantra is akin to a religious belief. Making this claim for these vaccines is especially untethered to reality or science.

110. The science was purportedly "settled" for decades that the pertussis vaccine prevented infection and transmission of pertussis, and hence the medical community engaged in a worldwide campaign to "eradicate" pertussis through pertussis vaccination. It is only in the last few years that scientists have finally realized that the pertussis vaccine does not prevent individuals from becoming infected and transmitting pertussis. In fact, the science now demonstrates that the pertussis vaccine has increased the amount of circulating pertussis since it turns vaccinated individuals into repeat asymptomatic carriers of pertussis.

111. The science is clearly not "settled" with regard to whether DTaP/Tdap cause over 90% of the serious injuries that federal health authorities asserts are the most commonly claimed injuries to result from these products. (*Supra* § IV.) In fact, even though there is scientific evidence that aluminum, used as adjuvants in DTaP/Tdap, can cause cancer, mutate genes and impair fertility, these products have never even been evaluated for their potential to cause cancer, mutate genes or cause infertility. *See, e.g.*, https://www.fda.gov/media/75157/download ("INFANRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.")

112. The science was purportedly long-settled that tetanus, diphtheria and pertussis vaccines reduced infant mortality. However, when this belief was finally tested in the first ever

natural experiment performed on populations in Africa, the finding was that children vaccinated with tetanus, diphtheria and pertussis containing vaccine in the first six months of life died at 10 times the rate as those that received no vaccines during this period. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/). This study was the endcap to a long line of recent studies which similarly found the children vaccinated with this vaccine had increased mortality versus the unvaccinated.

113. As a final example, one must look at the most controversial of the claimed vaccine injuries and the one HHS and CDC declare they have completely and thoroughly studied: autism. A significant portion of parents with autistic children claim routine vaccines injected during the first six months of life – DTaP, Hep B, Hib, PCV13, and IPV, each injected 3 times by 6 months – are a cause of their child's autism. The CDC tells these parents that "Vaccines Do Not Cause Autism." However, no study exists to support this claim for any of the vaccines given during the first six months of life.

114. With regard to DTaP, the 1986 Act required HHS to address whether pertussis-containing vaccines can cause autism (https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf) and HHS, in turn, commissioned the IOM to answer this question. The IOM conducted this review and issued its report in 1991 which stated it could not identify a single study which supports that the pertussis vaccine does not cause autism. (https://www.nap.edu/read/1815/chapter/7?term=autism#152). Nearly 22 years later, in 2012, the CDC commissioned the IOM to again assess whether the pertussis vaccine (as well as tetanus and diphtheria vaccines) cause autism, as this remained, according to the CDC, one of the most commonly claimed injuries from this vaccine. (https://www.nap.edu/read/13164/chapter/2#2). As in 1991, the IOM concluded in 2012 that it could not locate a single study supporting that pertussis, diphtheria or

tetanus containing vaccines do not cause autism. (https://www.nap.edu/read/13164/chapter/12#545). HHS was also unable to produce any such study as of 2018. (https://www.icandecide.org/wp-content/uploads/2019/08/ICAN-Reply-1.pdf § VI). (Similarly, no study exists to support that Hep B, Hib, PCV 13, and IPV vaccines do not cause autism. *Id*.)

115. The only vaccine the CDC has actually studied with regard to autism is MMR (the measles, mumps, and rubella vaccine) and those studies have been mired in controversy. For example, a Senior CDC Scientist claims the CDC did find an increased rate of autism after MMR, depending on the age of administration, in the only MMR/autism study ever conducted by the CDC with American children (https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio; https://www.c-span.org/video/?c4546421/rep-bill-posey-calling-investigation-cdcs-mmr-research-fraud) and HHS's primary autism expert in Vaccine Court recently provided an affidavit explaining that vaccines can cause autism in some children (https://bit.ly/2MEUP8I). But even putting this aside, the lack of even a single study to support that DTaP (nor any other of the four vaccines injected three times each during the first six months of life) does not cause autism, renders the CDC's declaration that "Vaccines Do Not Cause Autism" a belief, not science.

116. And autism is the claimed vaccine injury HHS, CDC and the NYSDOH claim to have most thoroughly studied. The state of the science for the numerous other immune, neurological and chronic health issues claimed to result from vaccination have even less scientific study. The NYSDOH nonetheless demands that plaintiffs and all other New Yorkers believe their vaccine claims and submit to such vaccines or else be expelled from school.

117. The NYSDOH seeks to convince parents of its belief in vaccines on its webpage titled "Vaccine Safety" which begins with a section entitled "Get the Facts" and states that: "Trustworthy sources do not hide their identity. They do not threaten or attack people who don't

share their views." Plaintiff agrees that trustworthy people do not threaten or attack people who don't share their views by, for example, expelling or threatening to expel her child from school.

VI. Medical Exemptions in New York for DTaP, Tdap, or IPV

118. With the repeal of the Religious Exemption on June 13, 2019, every parent who wants to send their child to school in New York must accept the NYSDOH's beliefs regarding DTaP/Tdap and IPV. The only exemption available now under PHL § 2164 for attending school without DTaP/Tdap or IPV is if a "physician licensed to practice medicine in this state certifies that such immunization may be detrimental to a child's health." PHL § 2164(8). The NYSDOH, however, in furtherance of its beliefs regarding vaccines, has gutted this exemption by limiting it to only permitting a medical exemption if it is based on the CDC's strict contraindication list. And the only basis, under the CDC's contraindication list for not receiving a DTaP/Tdap or IPV vaccine, is if the child has already had anaphylaxis (life threatening allergic reaction) or encephalopathy (brain damage) from a prior dose of DTaP/Tdap or IPV. (https://www.health.ny.gov/forms/doh-5077.pdf). Meaning, a child needs to have almost died or suffered brain damage following a prior dose to obtain a medical exemption and attend school without any further doses of DTaP, Tdap, or IPV. When a child suffers any of the other over one hundred serious injuries commonly reported after these vaccines, and which even their manufacturer GSK and Sanofi have a basis to disclose may be causally related to their product, no medical exemption is permitted.

119. Since it is medically accepted that various factors can render a child susceptible to vaccine harm (*supra* § IV), parents and their children's doctors should have the discretion to decide whether to inject these products, especially when there are gaps in the data or scientific literature. However, instead of leaving parents and doctors to make a medical decision for a child regarding tetanus, diphtheria or pertussis containing vaccine in these situations, the CDC and NYSDOH do

precisely the opposite. The CDC has published an extensive *anti*-contraindication document entitled "Conditions Commonly Misperceived as Contraindications to Vaccination" which the NYSDOH follows in deciding upon whether a medical exemption is appropriate.

TABLE 4-2. Conditions incorrectly perceived as contraindications or precautions to vaccination (i.e., vaccines may be given under these conditions)

Vaccine	Conditions commonly misperceived as contraindications or precautions
DTaP	Fever within 48 hours after vaccination with a previous dose of DTP or DTaP Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP Seizure ≤3 days after receiving a previous dose of DTP/DTaP Persistent, inconsolable crying lasting ≥3 hours within 48 hours after receiving a previous dose of DTP/DTaP Family history of seizures Family history of sudden infant death syndrome Family history of an adverse event after DTP or DTaP administration Stable neurologic conditions (e.g., cerebral palsy, well-controlled seizures, or developmental delay)

120. For example, the CDC specifically provides that a "[f]amily history of an adverse event after DTP or DTaP" is not a "contraindication." Thus, a parent cannot obtain a medical exemption from DTaP even where a sibling or even an identical twin died or suffered brain damage from a DTaP vaccine. Similarly, the CDC states that "Family history of seizures" or even "well-controlled seizures" are *not* contraindications to DTaP vaccine. The CDC cannot have reached this conclusion scientifically when the IOM found there was insufficient science to even determine whether seizures are caused by DTaP. (https://www.nap.edu/read/13164/chapter/2#4). The CDC similarly says that "Family history of sudden infant death syndrome" ("**SIDS**") is *not* a contraindication to DTaP, even when the IOM found that there was insufficient science to even determine whether DTaP causes SIDS. (https://www.nap.edu/read/13164/chapter/2#8).

121. A parent, therefore, cannot abstain in New York from giving DTaP to their child even when their child's sibling or even identical twin – with a similar or even identical genetic

blueprint – developed a serious seizure disorder or died following a DTaP vaccine. Even the child that developed a seizure disorder cannot obtain a medical exemption even though seizure disorders from pertussis-containing vaccines are routinely compensated in Vaccine Court. The CDC even proclaims that a "[h]istory of brachial neuritis" (a disease characterized by pain or loss of function in the nerves that carry signals to and from the brain and spinal column) is not a contraindication to DTaP/Tdap, even though the IOM in 1994 found that "the evidence favors a causal relation" between tetanus and diphtheria vaccine and brachial neuritis. (https://www.nap.edu/read/2138/chapter/2#13). Even if a sibling or identical twin suffers brain damage from a DTaP vaccine, which the CDC accepts as a contraindication to this vaccine, the sibling (even an identical twin) cannot obtain a medical exemption in New York.

122. When health authorities are not even conducting the studies to determine which injuries are actually caused by DTaP/Tdap or IPV, let alone which child is susceptible to injury, to prohibit medical exemptions (beyond anaphylaxis or encephalopathy from a prior dose) is a violation of the right to life and liberty. It is indefensible that liability-free pharmaceutical companies and the federal department responsible for vaccine safety do not perform this science. Where private interests are both profiting and spending billions of dollars promoting and distributing these products, it is scientifically indefensible to deprive a parent of the right to informed consent. The ability to *withhold* consent without the coercive threat of expulsion from school is the only protection that a child has where the child's parent or doctor perceives a heightened risk of harm.

123. While every dose of GSK's DTaP or Sanofi's DTaP or IPV is purported to be the same, every child is different. All three IOM reports clearly and expressly acknowledge that susceptibility to a serious adverse reaction must be done on an individual basis, considering, *inter*

alia, the specific child's personal genetics, personal behaviors, microbiome composition, intervening illness, developmental stage, and present and past environmental exposure. (https://www.nap.edu/read/13164/chapter/5#82).

124. While most parents have six injections of DTaP/Tdap and four injections of IPV administered to their children, some choose to delay or skip one or more of these doses precisely because they assessed the heighted risk of individual harm to the most important person in their lives. This is an assessment that must be left in the hands of the child's parent and doctor. The scientific community cannot stand behind the tetanus, diphtheria, pertussis and IPV-containing vaccines on the basis of scientific principle, when science has neglected even to identify what adverse reactions are causally related to these vaccines, let alone identify beforehand those who are susceptible to serious vaccine reactions, including death.

VII. New York Eliminated Religious Exemption to Vaccination

125. The relief valve for the foregoing gap in scientific knowledge regarding DTaP/Tdap and IPV was bridged by the existence of a religious exemption to vaccination in New York. In 1964, when the Legislature added Section 2164 to the Public Health Law, it listed only one required vaccine to attend school and provided that children could still attend school without this vaccine if their parent held a religious belief that prevented administering this vaccine (the "**Religious Exemption**"). (L 1966, ch. 994.)

126. The Religious Exemption was eliminated by the New York legislature on June 13, 2019 for all vaccines, including DTaP, Tdap, and IPV vaccine. (L. 2019, ch. 35.) As noted, the medical exemption is patently insufficient because the only grounds for a medical exemption under New York law for these vaccines is if the child has already had anaphylaxis (life threatening allergic reaction) or encephalopathy (brain damage) from a prior dose.

127. Plaintiff has concerns about her child's auto-immune and central nervous systems based on I.R.'s medical history and how vaccines may or may not be related to these concerns. Plaintiff, early on, turned to the medical community. When the medical community did not have answers, Plaintiff turned to a higher authority, as it were. She has a belief against subjecting her child to a medical procedure where she has assessed that the potential risks outweigh the potential benefits.

128. Plaintiff, as a parent, therefore claimed a religious exemption from further vaccination for tetanus, diphtheria, pertussis, and IPV vaccines since her beliefs prohibits her from injecting her child with a product where she believes the risks outweigh the benefits. The religious exemption thereafter acted as a release valve for the gap in scientific knowledge with regards to GSK and Sanofi's DTaP/Tdap and IPV products. With the elimination of this right, Plaintiff is left with having to choose between, on the one hand, injecting her child with products in violation of her belief to protect her child and, on the other hand, having her child excluded from school.

129. Plaintiff should not have to make this choice because the State does not have a compelling interest, let alone a rational basis, to exclude her child from school for not having an additional dose of these vaccine products.

FIRST CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Fundamental Right to Bodily Integrity

130. The preceding paragraphs are hereby realleged and incorporated herein by reference.

131. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

132. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Based on her intimate knowledge of her child, including her child's individual medical and familial histories, and her knowledge regarding the pertussis vaccine, Plaintiff and her child oppose injecting this product into the child's body.

133. PHL 2164 and 10 NYCRR § 66-1.1(f) require expulsion of a student from school in New York who is not injected with a certain number of doses of pertussis containing vaccine.[3]

134. Conditioning school attendance upon the injection of a pertussis containing vaccine, when the child and the child's parents object to this injection, infringes upon the fundamental right to bodily integrity.

135. Prior court decisions have found that a compelling state interest to control the spread of infection from student-to-student can trump certain constitutional rights in certain situations. This compelling state interest is absent with regard to vaccination for pertussis since this vaccine does not prevent the vaccinated student from becoming infected and transmitting pertussis. *See, e.g.,* Vaccine (2018) https://www.ncbi.nlm.nih.gov/pubmed/29180031 ("neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the [pertussis] pathogen") *and* Frontiers in Immunology (2019) https://pubmed.ncbi.nlm.nih.gov/31333640/ ("aPVs [acellular pertussis vaccines] … can prevent disease but cannot avoid infection and transmission"). It only affords personal protection by reducing the symptoms of pertussis for the vaccinated child.

136. In fact, the form of immunity created by the pertussis vaccine renders those vaccinated susceptible to become repeatedly infected with pertussis bacteria while not presenting

[3] Prior to seven years of age, a student is required to have four or five doses to attend school. Between seven and eighteen years of age, a student is only required to have one dose to attend school (depending on age of administration). Upon turning eighteen years of age, a student is not required to have any doses to attend school.

symptoms. Meaning, those vaccinated for pertussis can repeatedly become infected and are capable of transmitting pertussis while remaining asymptomatic (presenting no symptoms) or paucisymptomatic (presenting few symptoms). On the other hand, the student that is not vaccinated for pertussis may become infected with pertussis bacteria once, will have symptoms and know to stay home, and for many years thereafter will have immunity that prevents the student from becoming re-infected and transmitting pertussis. *Id.* ("in contrast to prior infection [with pertussis], current pertussis vaccines do not prevent asymptomatic infection").

137. Hence, excluding a child from school as a means to compel injection of the pertussis vaccine does not pass strict scrutiny. There is also no rational basis to exclude a child from school for not receiving the pertussis vaccine since those vaccinated with the pertussis vaccine are more likely to spread the pertussis bacteria.

138. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require vaccination for pertussis to attend school, should be struck down for violating the fundamental right to bodily integrity under the United States Constitution and the New York State Constitution.

SECOND CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Fundamental Right to Informed Consent

139. The preceding paragraphs are hereby realleged and incorporated herein by reference.

140. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

141. Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent

to the medical procedure. Plaintiff has reviewed the risks and benefits of the pertussis vaccine and, based on that review and her intimate knowledge of her child, including her child's medical and family history, cannot consent to injecting this product into her child.

142. Conditioning school attendance upon the injection of a pertussis vaccine where the child's parent has made an informed decision to not administer this product to their child infringes upon the fundamental right to informed consent.

143. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

144. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

THIRD CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Fundamental Right to Parental Choice

145. The preceding paragraphs are hereby realleged and incorporated herein by reference.

146. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

147. Coercing a parent to vaccinate their child by conditioning school attendance upon the injection of a pertussis-containing vaccine where the child's parent has chosen to not administer this product to their child infringes upon their fundamental right of parental choice.

148. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

149. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

FOURTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Substantive Due Process Right to Liberty

150. The preceding paragraphs are hereby realleged and incorporated herein by reference.

151. The United States Constitution and the New York State Constitution guarantee the substantive due process right to liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

152. It is a deprivation of Plaintiff's and her child's substantive due process right to liberty to coerce a parent under threat of expelling their child from school to inject their child with a liability-free product when their informed decision based on review of the existing literature regarding this product and their intimate knowledge of their child, including the child's medical and familial history, is to not inject their child with this product.

153. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

154. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to liberty under the United States Constitution and the New York State Constitution.

FIFTH CAUSE OF ACTION

Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Substantive Due Process Right to Life

155. The preceding paragraphs are hereby realleged and incorporated herein by reference.

156. As discussed above, the pertussis vaccine can cause some children to die as a result of being vaccinated. The research has not yet been done to know which children are susceptible to die from this product. Administering a pertussis vaccine could deprive a child of life. Plaintiff has concluded that her child has a heightened risk of serious injury from this product and opposes injecting this product into her child.

157. The United States Constitution and the New York State Constitution guarantee the fundamental substantive due process right of life which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

158. Conditioning school attendance upon the injection of a pertussis vaccine where the child's parent has chosen to not administer this product to their child and there is no science to validate that their child will not die from this product, infringes upon their and their child's fundamental right to life.

159. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

160. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to life under the United States Constitution and the New York State Constitution.

SIXTH CAUSE OF ACTION

Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Fundamental Right to Free Exercise of Religion

161. The preceding paragraphs are hereby realleged and incorporated herein by reference.

162. Plaintiff is fully competent and able to make decisions based on the best interests of her child and has concluded that the risks of injecting the pertussis vaccine into her child outweigh the benefit for her child and her religious beliefs therefore prevents her from injecting this product into her child.

163. The research has not yet been done to know which children are susceptible to be seriously injured or die from this product. Plaintiff's informed assessment is that the risk of serious injury or death from this product to her child is greater than the risk of serious injury or death from pertussis and hence administering this product to her child violates her religious beliefs.

164. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

165. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

166. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

SEVENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Pertussis Vaccine Violates the Right to an Education

167. The preceding paragraphs are hereby realleged and incorporated herein by reference.

168. The New York State Constitution at Article XI guarantees a right to an education.

169. Conditioning school attendance upon the injection of a pertussis containing vaccine, when the Plaintiff has made the informed and constitutionally-protected decision to not inject her child with an additional does of a pertussis vaccine, violates the parent's and child's right under New York State constitutional to obtain an education.

170. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to the pertussis vaccine.

171. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the right to an education under the New York State Constitution.

EIGHTH CAUSE OF ACTION
Expelling a Student From School for Not Being Injected With the Pertussis Vaccine Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Liberty, Substantive Due Process Right to Life, Free Exercise of Religion, and the Right to an Education

172. The preceding paragraphs are hereby realleged and incorporated herein by reference.

173. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the FIRST through SEVENTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

NINTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Right to Bodily Integrity

174. The preceding paragraphs are hereby realleged and incorporated herein by reference.

175. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

176. PHL 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York if they have not received a certain number of doses of pertussis containing vaccines.

177. Plaintiff is fully competent and able to make decisions based on the best interests of her child and objects to injecting her child with a product that creates a defective form of immunity that will render her child chronically susceptible to become infected with and transmit pertussis.

178. Pertussis vaccines are designed to generate antibodies to antigens secreted by or found on the surface of the pertussis bacteria. The genome of the pertussis bacteria (i.e., its total number of genes) is estimated to have approximately 3,000 genes, many of which encode surface or secreted proteins. All pertussis containing vaccines used in the United States contain only 5 of these antigens, and hence can only generate antibodies to 5 of the numerous antigens on the surface of or secreted by the pertussis bacteria.

179. By generating antibodies to only 5 of the surface antigens and secreted toxins of the pertussis bacteria, the result is that the vaccinated person may have few or no symptoms if infected with pertussis but will still become colonized with and silently transmit pertussis.

180. This defective immunity remains even after an individual vaccinated for pertussis becomes infected with pertussis. The body of a pertussis-vaccinated individual will continue to

generate a vigorous immune response only to the 5 antigens included in the pertussis vaccine, but not to other pertussis antigens. This defective immune response appears to remain irrespective of how many times the individual vaccinated for pertussis is infected with pertussis.

181. This defective immunity is caused by what is known as "linked epitope suppression" which locks in the initial immune response created by the 5 select antigens in the pertussis vaccine. An epitope is the portion of the antigen to which an antibody will bind. Since the pertussis vaccine generates antibodies to only 5 epitopes (antigens) of the pertussis bacteria, when the body later encounters the pertussis bacteria, it generates antibodies to these five antigens but does not generate antibodies to the other surface antigens of the pertussis bacteria that might be crucial for preventing further re-infection. Due to "linked epitope suppression," the generation of antibodies to the five epitopes from the pertussis vaccine suppresses the creation of antibodies to a broader range of other epitopes that comprise the pertussis bacteria.

182. In contrast, an unvaccinated individual that has had pertussis will have generated antibodies to the broad array of pertussis antigens, and when re-exposed to pertussis, their antibodies immediately coat the pertussis bacteria and prevent them from colonizing the host's respiratory tract.

183. The defective immunity to pertussis created by the pertussis vaccine appears to remain for the entire lifetime of the vaccinated individual. This renders individuals vaccinated for pertussis susceptible to repeatedly become infected with pertussis bacteria, potentially every few weeks for the rest of their life.

184. Plaintiff opposes injecting the pertussis vaccine into her child and creating this form of defective immunity in her child's body and, as described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for

school in order to prevent student-to-student infection is absent with regard to the pertussis vaccine.

185. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to bodily integrity.

TENTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Fundamental Right to Informed Consent

186. The preceding paragraphs are hereby realleged and incorporated herein by reference.

187. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

188. As described in preceding paragraphs, which are incorporated herein by reference, pertussis vaccine creates a defective immunity that renders those receiving this product subject to chronic repeat infection with pertussis for the rest of their lives; and pursuant to PHL 2164 and 10 NYCRR § 66-1.1(f), Plaintiff's child will be excluded from school despite her informed decision to not inject this product into her child.

189. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

ELEVENTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Fundamental Right to Parental Choice

190. The preceding paragraphs are hereby realleged and incorporated herein by reference.

191. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

192. Plaintiff is fully competent and able to make decisions based on the best interests of her child.

193. As described in paragraphs 179 through 186, which are incorporated herein by reference, the pertussis vaccine creates a defective immunity that renders those receiving this product subject to chronic repeat infection with pertussis for the rest of their lives; and pursuant to PHL 2164 and 10 NYCRR § 66-1.1(f), Plaintiff's child will be excluded from school despite her informed decision to not inject this product into her child.

194. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

TWELFTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Substantive Due Process Right to Life and Liberty

195. The preceding paragraphs are hereby realleged and incorporated herein by reference.

196. The United States Constitution and the New York State Constitution guarantee the substantive due process right to life and liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

197. As described in paragraphs preceding paragraphs, which are incorporated herein by reference, the pertussis vaccine creates a defective immunity that renders those receiving this product subject to chronic repeat infection with pertussis for the rest of their lives.

198. It is a deprivation of Plaintiff's and her child's substantive due process right to life and liberty to coerce them under threat of expulsion from school to be injected with a liability-free product when her informed decision based on review of the existing literature regarding this product, is to not inject her child with this product.

199. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to life and liberty under the United States Constitution and the New York State Constitution.

THIRTEENTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Fundamental Right to Free Exercise of Religion

200. The preceding paragraphs are hereby realleged and incorporated herein by reference.

201. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

202. As described in preceding paragraphs, which are incorporated herein by reference, the pertussis vaccine creates a defective immunity that renders those receiving this product subject to chronic repeat infection with pertussis for the rest of their lives; and pursuant to PHL 2164 and 10 NYCRR § 66-1.1(f), Plaintiff's child will be excluded from school despite opposing injecting her child with this product.

203. Plaintiff believes that the human body was created in the image of God and that damaging His creation by injecting this product into their child's body violates her religious belief.

204. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

FOURTEENTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates the Right to an Education

205. The preceding paragraphs are hereby realleged and incorporated herein by reference.

206. The New York State Constitution at Article XI guarantees a right to an education.

207. As described in paragraphs 179 through 186, which are incorporated herein by reference, the pertussis vaccine creates a defective immunity that renders those receiving this product subject to chronic repeat infection with pertussis for the rest of their lives, and pursuant to PHL 2164 and 10 NYCRR § 66-1.1(f) Plaintiff's child will be excluded from school despite opposing injecting this product into her child.

208. Conditioning school attendance upon the injection of a tetanus vaccine, when the Plaintiff has made the informed and constitutionally-protected decision to not vaccinate her child with an additional dose of a pertussis containing vaccine, violates Plaintiff's and her child's right under the New York State Constitution to obtain an education.

209. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the right to an education under the New York State Constitution.

FIFTEENTH CAUSE OF ACTION
Conditioning a Government Benefit Upon Injection of a Product that Creates Defective Immunity Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Life and Liberty, Free Exercise of Religion, and the Right to an Education

210. The preceding paragraphs are hereby realleged and incorporated herein by reference.

211. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the NINTH through FOURTEENTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

SIXTEENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Right to Bodily Integrity

212. The preceding paragraphs are hereby realleged and incorporated herein by reference.

213. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

214. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Based on her intimate knowledge of her child, including her child's individual medical and familial histories, and their knowledge regarding the tetanus vaccine, Plaintiff and her child do not want another dose of a tetanus containing vaccine injected into the child's body.

215. PHL 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York without receiving a certain number of doses of tetanus containing vaccine.[4]

[4] For a student six years of age and younger, four or five doses are required to attend school (depending on age of administration). For a student older than six years of age and born after January 1, 2005, three to five doses are required to attend school (depending on age of administration). For a student born before January 1, 2005, is entering sixth grade or above, and is younger than eighteen years of age, one dose is required to attend school. For a student eighteen years of age and older, no doses are required to attend school.

216. Conditioning school attendance upon the injection of a tetanus vaccine, when the Plaintiff and her child object to this injection, infringes upon the fundamental right to bodily integrity.

217. Prior court decisions have found that a compelling state interest to prevent the spread of an infection from student-to-student can trump certain constitutional rights in certain situations. This compelling state interest is absent with regard to vaccination for tetanus since it is not communicable (transmissible from person-to-person). *See, e.g.,* https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html ("Tetanus is not contagious from person to person.") A student with tetanus cannot spread tetanus to another student.

218. Because tetanus is not contagious from person-to-person, a student cannot contract or transmit tetanus from or to another student in school. Tetanus vaccine does not prevent infection or transmission of tetanus from person-to-person of tetanus since tetanus is not contagious from person-to-person. Neither a student with current tetanus vaccination nor a student without any tetanus vaccine can infect another child with tetanus. Plaintiff's child cannot contract or transmit tetanus to any student in her school because tetanus is not contagious from person-to-person.

219. Hence, compelling the injection of tetanus vaccine into a Plaintiff's child against heir informed decision under duress of expelling her child from school does not pass strict scrutiny. There is also no rational basis to exclude Plaintiff's child from school for not having a tetanus vaccine since those vaccinated with a tetanus vaccine are no more or less likely to spread tetanus in school because it is not contagious from person-to-person.

220. Expelling a child from school is also not the least restrictive means because there were effectively no cases among school-aged children in New York before requiring tetanus vaccine to attend school in New York State, making it clear that preventing tetanus among school-

aged children had already been achieved without needing to expel all students in New York State from school for not receiving this product.

221. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the right to bodily integrity.

SEVENTEENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Fundamental Right to Informed Consent

222. The preceding paragraphs are hereby realleged and incorporated herein by reference.

223. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

224. Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent to the medical procedure. Plaintiff has reviewed the risks and benefits of the tetanus vaccine and, based on that review and her intimate knowledge of her child, including her child's medical and family history, does not consent to injecting this product into her child.

225. Conditioning school attendance upon the injection of a tetanus vaccine where the child's parent has made an informed decision to not administer this product to their child infringes upon the fundamental right to informed consent.

226. As described in paragraphs 216 through 222, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to tetanus vaccine.

227. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

EIGHTEENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Fundamental Right to Parental Choice

228. The preceding paragraphs are hereby realleged and incorporated herein by reference.

229. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

230. Coercing a parent to vaccinate their child by conditioning school attendance upon the injection of a tetanus containing vaccine where the child's parent has chosen to not administer this product to their child infringes upon the fundamental right of parental choice.

231. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to tetanus vaccines.

232. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

NINETEENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Substantive Due Process Right to Liberty

233. The preceding paragraphs are hereby realleged and incorporated herein by reference.

234. The United States Constitution and the New York State Constitution guarantee the substantive due process right to liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

235. It is a deprivation of Plaintiff's and her child's substantive due process right to liberty to coerce parents to inject her child with a liability-free product under threat of expelling her child from school when her informed decision based on review of the existing literature regarding this product and her intimate knowledge of her child, including the child's medical and familial history, is to not inject her child with this product.

236. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to tetanus vaccine.

237. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the fundamental right to liberty under the United States Constitution and the New York State Constitution.

TWENTIETH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Substantive Due Process Right to Life

238. The preceding paragraphs are hereby realleged and incorporated herein by reference.

239. Some children can die from receiving a tetanus vaccine. The research has not yet been done to know which children are susceptible to die from this product. Administering a tetanus

vaccine could deprive a child of life. Plaintiff has concluded her child has an increased risk of harm from the tetanus vaccine and oppose injecting this product into her child.

240. The United States Constitution and the New York State Constitution guarantee the fundamental substantive due process right of life which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

241. Conditioning school attendance upon the injection of a tetanus vaccine where the child's parent has chosen to not administer this product to their child, and where there is no science to validate that their child will not die from this product, infringes upon their and the parents and their child's fundamental right to life.

242. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school to prevent student-to-student transmission of infection is absent with regard to tetanus vaccine.

243. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the fundamental right to life under the United States Constitution and the New York State Constitution.

TWENTY-FIRST CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Fundamental Right to Free Exercise of Religion

244. The preceding paragraphs are hereby realleged and incorporated herein by reference.

245. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

246. The research has not yet been done to know which children are susceptible to serious injured or death from this product. Plaintiff's informed assessment is that the risk of

serious injury or death from this product to her child is greater than the risk of serious injury or death from tetanus and hence administering this product to her child violates their religious beliefs.

247. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school to prevent student-to-student infection is absent with regard to tetanus vaccine.

248. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

TWENTY-SECOND CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Tetanus Vaccine Violates the Right to an Education

249. The preceding paragraphs are hereby realleged and incorporated herein by reference.

250. The New York State Constitution at Article XI guarantees a right to an education.

251. Conditioning school attendance upon the injection of a tetanus vaccine, when the Plaintiff has made the informed and constitutionally-protected decision to not vaccinate her child with an additional dose of a tetanus containing vaccine, violates Plaintiff's and her child's right under the New York State Constitution to obtain an education.

252. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school to prevent student-to-student infection is absent with regard to tetanus vaccine.

253. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for tetanus to attend school should be struck down for violating the right to an education under the New York State Constitution.

TWENTY-THIRD CAUSE OF ACTION

Expelling a Student From School for Not Being Injected With the Tetanus Vaccine Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Liberty, Substantive Due Process Right to Life, Free Exercise of Religion, and the Right to an Education

254. The preceding paragraphs are hereby realleged and incorporated herein by reference.

255. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the SIXTEENTH through TWENTY-SECOND CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

TWENTY-FOURTH CAUSE OF ACTION

Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Fundamental Right to Bodily Integrity

256. The preceding paragraphs are hereby realleged and incorporated herein by reference.

257. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

258. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Based on her intimate knowledge of her child, including her child's individual medical and familial histories, and their knowledge regarding the diphtheria vaccine, Plaintiff and her child do not want another dose of a diphtheria-containing vaccine injected into her body.

259. PHL 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York without receiving a certain number of doses of diphtheria-containing vaccine.[5]

[5] Prior to the sixth grade, a student is required to have between three and five doses to attend school (depending on age of administration). Between sixth grade but before eighteen years of age, a student is required to have three doses to attend school. A student eighteen years or age or older is not required to have any doses to attend school.

260. Conditioning school attendance upon the injection of a diphtheria vaccine into a child's body, when the child and the child's parents object to this injection, infringes upon the fundamental right to bodily integrity.

261. Prior court decisions have found that a compelling state interest to prevent the spread of an infection from student-to-student can trample on certain constitutional rights in certain situations. This compelling state interest is absent with regard to vaccination for diphtheria since this vaccine does not prevent person-to-person transmission of diphtheria because it only creates antibodies to a toxin released by the diphtheria bacteria but does not generate any antibodies to the diphtheria bacteria itself. *See, e.g.*, American Journal of Diseases of Children (1972) https://www.ncbi.nlm.nih.gov/pubmed/5026197 ("Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection.").

262. The diphtheria bacteria can sometimes cause clinical symptoms when it releases a particular toxin. The diphtheria vaccine contains a modified form of this toxin. The diphtheria vaccine does not contain any portion of the diphtheria bacteria itself. This vaccine therefore does not generate any antibodies that would target the diphtheria bacteria. It only generates antibodies against a toxin sometimes released by these bacteria. The diphtheria vaccine therefore does not prevent carriage and transmission of the diphtheria bacteria from person-to-person. *Id.* ("[T]here is no difference in the risk of diphtheria acquisition among those with full, lapsed, inadequate, and no immunizations. … [D]iphtheria outbreaks have been described in populations with as much as 94% of the people being previously immunized. These outbreaks, the known importance of carriers in the spread of diphtheria, and the demonstrated failure of toxoid to prevent the carrier state lead us to conclude that the concept of herd immunity is not applicable in the prevention of diphtheria.")

263. According to the CDC, Diphtheria continues to circulate in the United States. After six doses of diphtheria vaccine, the immunity wanes rapidly such that adults are, according to the CDC, supposed to receive a diphtheria booster every ten years over their entire lifetime (https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html; https://www.health.ny.gov/publications/2391.pdf), yet 40% of adults do not obtain these boosters (https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html#tetanus) and even 16% of children do not have four or more doses (https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf). Nonetheless, despite continuing to circulate, there have only been 2 clinical cases (meaning, manifesting toxin induced symptoms) of diphtheria in the last fifteen years in the United States. This may reflect the extensive literature which supports that the production or deleterious action of the diphtheria toxin is counteracted by iron, vitamin C, and vitamin B3, and deficiencies of these vitamins and minerals have mostly been eliminated in developed countries. (https://www.ncbi.nlm.nih.gov/pubmed/2151460; https://www.ncbi.nlm.nih.gov/pubmed/7830565; https://www.ncbi.nlm.nih.gov/pubmed/4326212; https://www.ncbi.nlm.nih.gov/pubmed/189004).

264. For example, scarlet fever – which, like diphtheria, is the result of another bacterium (Group A Streptococcus) releasing a symptom-producing toxin upon being lysogenized by an appropriate virus – was once a dreaded childhood disease and gradually disappeared in sync with the disappearance of diphtheria, despite the fact that no vaccine was ever successfully developed for scarlet fever. Numerous serious and intensive attempts to develop a vaccine for scarlet fever were unsuccessful and hence it is not listed as part of the CDC and NYSDOH's current vaccine schedule, nor is any pharmaceutical company selling this vaccine to a captive market of 78 million American children without risk of financial liability for injuries.

265. The value of the diphtheria vaccine in developed countries like the United States where serious nutritional deficiencies are now rare is questionable. But even if it that were not so, this vaccine does not prevent a person from becoming colonized and transmitting diphtheria as it only produces antibodies to a toxin released by the diphtheria bacteria and does not produce any antibodies to the diphtheria bacteria itself. A person vaccinated for diphtheria can become infected with and transmit diphtheria bacteria.

266. Expelling a child from school is also not the least restrictive means because there were effectively no cases in New York both before and after requiring the diphtheria vaccine to attend school in New York State, making it clear that preventing diphtheria had already been achieved without needing to expel all students in New York State from school who have not received this product.

267. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the right to bodily integrity.

TWENTY-FIFTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Fundamental Right to Informed Consent

268. The preceding paragraphs are hereby realleged and incorporated herein by reference.

269. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

270. Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent

to the medical procedure. Plaintiff has reviewed the risks and benefits of the diphtheria vaccine and based on that review and their intimate knowledge of her child, including her child's medical and family history, cannot consent to injecting this product into her child.

271. Conditioning school attendance upon the injection of a diphtheria vaccine where the child's parent has made an informed decision to not administer this product to their child infringes upon the fundamental right to informed consent.

272. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

273. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

TWENTY-SIXTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Fundamental Right to Parental Choice

274. The preceding paragraphs are hereby realleged and incorporated herein by reference.

275. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

276. Coercing a parent to vaccinate their child by conditioning school attendance upon the injection of a diphtheria-containing vaccine where the child's parent has chosen to not administer this product to their child infringes upon the fundamental right of parental choice.

277. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

278. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

TWENTY-SEVENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Substantive Due Process Right to Liberty

279. The preceding paragraphs are hereby realleged and incorporated herein by reference.

280. The United States Constitution and the New York State Constitution guarantee the substantive due process right to liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

281. It is a deprivation of Plaintiff's and her child's substantive due process right to liberty to be coerced, under threat of expelling the child from school, to inject her child with a liability-free product when her informed decision based on review of the existing literature regarding this product and her intimate knowledge of her child, including the child's medical and familial history, is to not inject her child with this product.

282. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

283. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the fundamental right to liberty under the United States Constitution and the New York State Constitution.

TWENTY-EIGHTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Substantive Due Process Right to Life

284. The preceding paragraphs are hereby realleged and incorporated herein by reference.

285. The United States Constitution and the New York State Constitution guarantee the fundamental substantive due process right of life which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

286. The diphtheria vaccine can cause some children to die as a result of receiving this product. The research has not yet been done to know which children are susceptible to die from this product. Administering the diphtheria vaccine can deprive a child of life. Plaintiff has concluded that her child has a heightened risk of serious injury from this product.

287. Conditioning school attendance upon the injection of a diphtheria vaccine where the child's parent has chosen to not administer this product to their child, and where there is no science to validate that their child will not die from this product, infringes upon the parents and their child's fundamental right to life.

288. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

289. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the fundamental right to life under the United States Constitution and the New York State Constitution.

TWENTY-NINTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Fundamental Right to Free Exercise of Religion

290. The preceding paragraphs are hereby realleged and incorporated herein by reference.

291. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

292. The research has not yet been done to know which children are susceptible to serious injury or death from this product. Plaintiff's informed assessment is that the risk of serious injury or death from this product to her child is greater than the risk of serious injury or death from tetanus, and hence administering this product to her child violates her religious beliefs.

293. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

294. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

THIRTIETH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Diphtheria Vaccine Violates the Right to an Education

295. The preceding paragraphs are hereby realleged and incorporated herein by reference.

296. The New York State Constitution at Article XI guarantees a right to an education.

297. Conditioning school attendance upon the injection of a tetanus vaccine, when the Plaintiff has made the informed and constitutionally-protected decision to not vaccinate her child

with an additional dose of a diphtheria-containing vaccine, violates Plaintiff's and her child's right under the New York State Constitution to obtain an education.

298. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the diphtheria vaccine.

299. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for diphtheria to attend school should be struck down for violating the right to an education under the New York State Constitution.

THIRTY-FIRST CAUSE OF ACTION
Expelling a Student from School for Not Being Injected With the Diphtheria Vaccine Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Liberty, Substantive Due Process Right to Life, Free Exercise of Religion, and the Right to an Education

300. The preceding paragraphs are hereby realleged and incorporated herein by reference.

301. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the TWENTY-FOURTH through THIRTIETH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

THIRTY-SECOND CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Fundamental Right to Bodily Integrity

302. The preceding paragraphs are hereby realleged and incorporated herein by reference.

303. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

304. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Based on her intimate knowledge of her child, including her child's individual medical and familial histories, and their knowledge regarding the polio vaccine, Plaintiff and her child do not want another dose of a polio vaccine injected into her body.

305. PHL 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York without receiving a certain number of doses of the polio vaccine.[6]

306. Conditioning school attendance upon the injection of a polio vaccine into a child's body, when the child and the child's parents object to this injection, infringes upon the fundamental right to bodily integrity.

307. Prior court decisions have found that a compelling state interest to prevent the spread of an infection from student-to-student can trample on certain constitutional rights in certain situations. This compelling state interest is absent with regard to vaccination for polio since the only polio vaccine currently used in the United States, the IPV vaccine, does not prevent becoming infected with and transmitting polio. It only affords potentially personal protection against paralytic polio.

308. This is because polio virus proliferates in the intestines and is transmitted through fecal to oral contamination, but IPV generates antibodies in the blood, not in the intestinal tract. *See* http://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/ ("IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces … IPV does not stop transmission of the virus.") Because IPV does not prevent infection from student-to-

[6] Prior to the kindergarten grade, a student is required to have three doses to attend school. Before kindergarten (depending on age of administration), a student is required to obtain a fourth dose of IPV. A student eighteen years or age or older is not required to have any doses to attend school.

student, Defendants again cannot rely on their desire to control infection as a means to create the necessary compelling state interest to deny Plaintiff and her child's constitutionally-protected rights.

309. Expelling a child from school is also not the least restrictive means because there were effectively no cases in New York in the year before and after requiring the polio vaccine to attend school in New York State, making it clear that preventing polio had already been achieved without needing to expel all students in New York State from school who have not received this product.

310. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the right to bodily integrity.

THIRTY-THIRD CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Fundamental Right to Informed Consent

311. The preceding paragraphs are hereby realleged and incorporated herein by reference.

312. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

313. Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent to the medical procedure. Plaintiff has reviewed the risks and benefits of the polio vaccine and based on that review and their intimate knowledge of her child, including her child's medical and family history, cannot consent to injecting this product into her child.

314. Conditioning school attendance upon the injection of a polio vaccine where the child's parent has made an informed decision to not administer this product to their child infringes upon the fundamental right to informed consent.

315. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the polio vaccine.

316. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

THIRTY-FOURTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Fundamental Right to Parental Choice

317. The preceding paragraphs are hereby realleged and incorporated herein by reference.

318. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

319. Coercing a parent to vaccinate their child by conditioning school attendance upon the injection of a polio-containing vaccine where the child's parent has chosen to not administer this product to their child infringes upon the fundamental right of parental choice.

320. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the polio vaccine.

321. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

THIRTY-FIFTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Substantive Due Process Right to Liberty

322. The preceding paragraphs are hereby realleged and incorporated herein by reference.

323. The United States Constitution and the New York State Constitution guarantee the substantive due process right to liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

324. It is a deprivation of Plaintiff's and her child's substantive due process right to liberty to be coerced, under threat of expelling the child from school, to inject her child with a liability-free product when her informed decision based on review of the existing literature regarding this product and her intimate knowledge of her child, including the child's medical and familial history, is to not inject her child with this product.

325. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school to prevent student-to-student infection is absent with regard to the polio vaccine.

326. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the fundamental right to liberty under the United States Constitution and the New York State Constitution.

THIRTY-SIXTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Substantive Due Process Right to Life

327. The preceding paragraphs are hereby realleged and incorporated herein by reference.

328. The United States Constitution and the New York State Constitution guarantee the fundamental substantive due process right of life which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

329. The polio vaccine can cause some children to die as a result of receiving this product. The research has not yet been done to know which children are susceptible to die from this product. Administering the polio vaccine can deprive a child of life. Plaintiff has concluded that her child has a heightened risk of serious injury from this product.

330. Conditioning school attendance upon the injection of a polio vaccine where the child's parent has chosen to not administer this product to their child, and where there is no science to validate that their child will not die from this product, infringes upon the parents and their child's fundamental right to life.

331. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the polio vaccine.

332. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the fundamental right to life under the United States Constitution and the New York State Constitution.

THIRTY-SEVENTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Fundamental Right to Free Exercise of Religion

333. The preceding paragraphs are hereby realleged and incorporated herein by reference.

334. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

335. The research has not yet been done to know which children are susceptible to serious injury or death from this product. Plaintiff's informed assessment is that the risk of serious injury or death from this product to her child is greater than the risk of serious injury or death from tetanus, and hence administering this product to her child violates her religious beliefs.

336. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the polio vaccine.

337. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

THIRTY-EIGHTH CAUSE OF ACTION
Expelling a Student from School for Not Being Injected with the Polio Vaccine Violates the Right to an Education

338. The preceding paragraphs are hereby realleged and incorporated herein by reference.

339. The New York State Constitution at Article XI guarantees a right to an education.

340. Conditioning school attendance upon the injection of a polio vaccine, when the Plaintiff has made the informed and constitutionally-protected decision to not vaccinate her child

with an additional dose of a polio, violates Plaintiff's and her child's right under the New York State Constitution to obtain an education.

341. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school in order to prevent student-to-student infection is absent with regard to the polio vaccine.

342. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for polio to attend school should be struck down for violating the right to an education under the New York State Constitution.

THIRTY-NINTH CAUSE OF ACTION
Expelling a Student From School for Not Being Injected With the Polio Vaccine Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Liberty, Substantive Due Process Right to Life, Free Exercise of Religion, and the Right to an Education

343. The preceding paragraphs are hereby realleged and incorporated herein by reference.

344. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the THIRTY-SECOND through THIRTY-EIGHTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

FORTIETH CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Fundamental Right to Bodily Integrity

345. The preceding paragraphs are hereby realleged and incorporated herein by reference.

346. The United States Constitution and the New York State Constitution guarantee the fundamental right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. Plaintiff opposes injecting her child with the 3,515 mcg to 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP

and one dose of Tdap required by PHL § 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child's body in order for her child to attend school over Plaintiff's informed decision violates Plaintiff's and her child's fundamental right to bodily integrity.

347. PHL§ 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York without receiving five doses of DTaP and one dose of Tdap, or an appropriate number of catch-up doses.

348. Depending on which brand of DTaP and Tdap are used for the six doses of DTaP/Tdap required for school under New York State law, a child will be administered between 3,515 mcg and 9,000 mcg of aluminum adjuvant from these products.

349. The following chart lists the amount of aluminum adjuvant, either aluminum hydroxide or aluminum phosphate, in each vaccine dose:

Type	Product	Manufacturer	mcg per dose	Adjuvant
DTaP	Infanrix	GSK	625	aluminum hydroxide
DTaP	Daptacel	Sanofi	1,500	aluminum phosphate
Tdap	Adacel	Sanofi	1,500	aluminum phosphate
Tdap	Boostrix	GSK	390	aluminum hydroxide
DT	DT	Sanofi	1,500	aluminum phosphate
Td	Tenivac	Sanofi	1,500	aluminum phosphate

350. All of the tetanus, diphtheria, and pertussis vaccines required for school in New York are injected into muscle tissue. These products introduce foreign proteins into the body in order to create an immune response, which in turn is intended to generate antibodies. However,

none of these vaccines contain live bacteria which would elicit an immune response by replicating and causing cellular death.

351. Instead, the pertussis vaccine contains a tiny portion of isolated pertussis bacterial proteins and modified pertussis toxin and the tetanus and diphtheria vaccines contain only a modified toxin released by these bacteria (typically inactivated with a treatment of formalin or formaldehyde). Injecting these bacterial proteins and modified toxins, with nothing more, would produce a weak or non-existent immune response.

352. Therefore, vaccines also contain an "adjuvant," a chemical substance intended to generate a significant sustained immune response. The intent is to "trick" the immune system into treating the poorly immunogenic (i.e., ability to provoke an immune response) biological matter in the vaccines into appearing dangerous in order to provoke an immune response. Adjuvants in the DTaP and Tdap vaccines required for school in New York contain either aluminum hydroxide or aluminum phosphate, referred to as "aluminum adjuvants."

353. The pertussis proteins and modified pieces of toxin from tetanus and diphtheria are absorbed onto the pieces of aluminum adjuvant. In each vaccine dose of DTaP and Tdap, there are tens of thousands of particles of aluminum adjuvant. Each of these tens of thousands of particles is typically between approximately .1 and 1 micron in size – relatively large in the world of small particles. To provide a sense of scale, a single ion of aluminum (denoted as Al3+) has a radius that is around 2,000 times smaller than the radius of a single micron of aluminum adjuvant.

354. Because aluminum adjuvant particles are cytotoxic, they cause (as they are designed to do) cellular death at the injection site in the muscle tissue. This cellular death is what causes an initial immune response at the injection site. Macrophages (Greek for "big eater") and

other immune cells flood into the injection site. Macrophages then engulf the aluminum adjuvant particles and antigens which are bound to the macrophages.

355. These macrophages then travel to sites within the immune system, including lymph nodes. At these sites, the macrophages present the antigens to lymphocytes (b-cells and t-cells) in order to stimulate production of antibodies to these antigens.

356. The aluminum adjuvant particles, which are bio persistent and cannot be metabolized or destroyed by immune cells, are then carried by those macrophages to other organs in the body, notably brain tissue, and deposit the aluminum adjuvant particles in these organs. Numerous studies demonstrate that injection of aluminum adjuvant increases brain aluminum content. For example, in one study, a dosage of 200 mcg/kg of aluminum adjuvant caused a 50-fold increase in brain aluminum content in mice. These measurements were performed 6 months after final injection reflecting that these aluminum particles remained in the brain. Another study found accumulation of aluminum adjuvant in the brain of mice up to one year after injection.

357. Aluminum ingested in the diet has very low oral absorption and is in a solubilized, Al3+ ionic form (not particulate form). In ionic form, aluminum is (mostly) excluded from the brain by the blood-brain barrier and can be excreted through the kidneys. These defenses are adequate for protecting the brain from natural levels of aluminum exposure. However, these protective mechanisms are unable to protect the brain from injected aluminum adjuvant particles. Aluminum adjuvant particles are too large to be removed by the kidneys, and are carried into the brain by macrophages, either across the blood-brain barrier or through lymphatic vessels leading into the brain. Several studies include images of aluminum particles in the brain tissue of various kinds of animals following vaccination, as well as images of aluminum particles in the brains of deceases humans who had neurological deficits.

358. Aluminum adjuvant in the brain can cause a release of interleukin IL-6 and microglial activation, which dozens of studies show can lead to neurological deficits. A number of studies have specifically shown that aluminum adjuvant injections in mice cause adverse effects at vaccine-relevant dosages. These include deficits in learning and memory, deficits in neuromuscular strength and function, and changes in locomotor activity and/or gait.

359. FDA regulations require that an "adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product" and that the

> amount of aluminum in the recommended individual dose of a biological product [which included vaccines] shall not exceed: (1) 0.85 milligrams if determined by assay; (2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or (3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe.

21 CFR 610.15(a). Despite this regulatory requirement, and the robust and repeatedly replicated science reflecting the dangers of injecting aluminum adjuvant, neither the FDA, CDC nor NIH has been able to produce a single study to support the safety of injecting aluminum adjuvant into the human body at any level, including the amount from one or more doses of DTaP/Tdap vaccine.

360. For example, the following Freedom of Information Act request was sent to the FDA:

> **Copies of any human or animal studies involving the subcutaneous or intramuscular injection of aluminum adjuvant relied upon by the FDA to establish the safety of injecting infants and children with aluminum hydroxide, aluminum phosphate or amorphous aluminum hydroxyphosphate sulfate.**

The same demand was also sent to the CDC and NIH, and the response received to-date has been that they do not have any studies responsive to this FOIA request.

361. The FDA did not even have a single study to produce in response to the following requests:

> **1. Copies of the studies relied upon by the FDA to support that aluminum adjuvant used in biological products does not adversely affect the safety of these products. NOTE: This tracks the language used in https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=610.15**
>
> **2. Copies of the studies relied upon by the FDA when adopting its regulation at 21 C.F.R. 610.15 that the "amount of aluminum in the recommended individual dose of a biological product shall not exceed: (1) 0.85 milligrams if determined by assay; (2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or (3) 1.25 milligrams determined by assay."**

362. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require injection of aluminum adjuvant to attend school should be struck down for violating the right to bodily integrity.

FORTY-FIRST CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Fundamental Right to Informed Consent

363. The preceding paragraphs are hereby realleged and incorporated herein by reference.

364. The United States Constitution and the New York State Constitution guarantee the fundamental right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. Based on Plaintiff's review of the available literature regarding aluminum adjuvants contained in the DTaP/Tdap vaccines, Plaintiff opposes injecting her child with the between 3,515 mcg and 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP and one dose of Tdap required by PHL § 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child in order to attend school over

Plaintiff's informed decision violates Plaintiff's and her child's fundamental right to informed consent.

365. As described in preceding paragraphs, which are incorporated herein by reference, tens of thousands of pieces of aluminum adjuvant in each dose of DTaP/Tdap are taken up by macrophages at the injection site for these products, deposited by the macrophages into the tissue of various organs in the body, most notably brain tissue, and therein can cause neurological dysfunction and disorders.

366. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which requires injection of aluminum adjuvant to attend school should be struck down for violating the fundamental right to informed consent under the United States Constitution and the New York State Constitution.

FORTY-SECOND CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Fundamental Right to Parental Choice

367. The preceding paragraphs are hereby realleged and incorporated herein by reference.

368. The United States Constitution and the New York State Constitution guarantee the fundamental right to parental choice which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Plaintiff opposes injecting her child with the between 3,515 mcg and 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP and one dose of Tdap required by PHL 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child in order to attend school over Plaintiff's informed decision violates Plaintiff's and her child's fundamental right to parental choice.

369. As described in preceding paragraphs, which are incorporated herein by reference, tens of thousands of pieces of aluminum adjuvant in each dose of DTaP/Tdap are taken up by macrophages at the injection site for these products, deposited by the macrophages into the tissue of various organs in the body, most notably brain tissue, and therein can cause neurological dysfunction and disorders.

370. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which requires injection of aluminum adjuvant to attend school should be struck down for violating the fundamental right to parental choice under the United States Constitution and the New York State Constitution.

FORTY-THIRD CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Substantive Due Process Right to Life and Liberty

371. The preceding paragraphs are hereby realleged and incorporated herein by reference.

372. The United States Constitution and the New York State Constitution guarantee the substantive due process right to life and liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. Plaintiff opposes injecting her child with the between 3,515 mcg and 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP and one dose of Tdap required by PHL § 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child in order to attend school over Plaintiff's informed decision violates Plaintiff's and her child's substantive due process right to life and liberty.

373. As described in preceding paragraphs, which are incorporated herein by reference, tens of thousands of pieces of aluminum adjuvant in each dose of DTaP/Tdap are taken up by macrophages at the injection site for these products, deposited by the macrophages into the tissue

of various organs in the body, most notably brain tissue, and therein can cause neurological dysfunction and disorders.

374. It is a deprivation of Plaintiff's and her child's substantive due process right to life and liberty to coerce a parent under threat of expelling her child from school to inject her child with a liability-free product that will introduce tens of thousands of particles of aluminum adjuvant into her child's body when her informed decision, based on review of the existing literature regarding aluminum adjuvant, is to not inject her child with these products.

375. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which requires injection of aluminum adjuvant in order for a child to attend school should be struck down for violating the fundamental right to life and liberty under the United States Constitution and the New York State Constitution.

FORTY-FOURTH CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Fundamental Right to Free Exercise

376. The preceding paragraphs are hereby realleged and incorporated herein by reference.

377. The United States Constitution and the New York State Constitution guarantee the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. Plaintiff opposes injecting her child with the between 3,515 mcg and 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP and one dose of Tdap required by PHL § 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child in order to attend school over Plaintiff's informed decision violates Plaintiff's and her child's fundamental right to free exercise of religion.

378. As described in preceding paragraphs, which are incorporated herein by reference, tens of thousands of pieces of aluminum adjuvant in each dose of DTaP/Tdap are taken up by macrophages at the injection site for these products, deposited by the macrophages into the tissue of various organs in the body, most notably brain tissue, and therein can cause neurological dysfunction and disorders.

379. Plaintiff believes that the human body was created in the image of God and that it would adulter God's creation to incorporate tens of thousands of particles of aluminum adjuvant into various body organs that have no therapeutic purpose, but are known to cause cellular and neuronal damage, as well as activate the release of cytokines which can cause damage to the brain.

380. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which requires injection of aluminum adjuvant to attend school should be struck down for violating the fundamental right to free exercise of religion under the United States Constitution and the New York State Constitution.

FORTY-FIFTH CAUSE OF ACTION
Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant into the Body in Order to Attend School Violates the Right to an Education

381. The preceding paragraphs are hereby realleged and incorporated herein by reference.

382. The New York State Constitution at Article XI guarantees a right to an education. Plaintiff opposes injecting their child with the between 3,515 mcg and 9,000 mcg of aluminum adjuvant contained in the five doses of DTaP and one dose of Tdap required by PHL § 2164 and 10 NYCRR § 66-1.1(f) to attend school. Requiring injection of this neuro-and-cyto-toxic substance into her child in order to attend school, over Plaintiff'' informed decision, violates the right to an education under the New York State Constitution.

383. As described in preceding paragraphs, which are incorporated herein by reference, tens of thousands of pieces of aluminum adjuvant in each dose of DTaP/Tdap are taken up by macrophages at the injection site for these products, deposited by the macrophages into the tissue of various organs in the body, most notably brain tissue, and therein can cause neurological dysfunction and disorders.

384. Conditioning school attendance upon the injection of tens of thousands of particles of aluminum adjuvant into the body, when Plaintiff has made the informed and constitutionally-protected decision to not vaccinate her child with this substance, violates Plaintiff's and her child's New York State constitutional right for her child to obtain an education.

385. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for pertussis to attend school should be struck down for violating the right to an education under the New York State Constitution.

FORTY-SIXTH CAUSE OF ACTION

Requiring Injection of Between 3,515 and 9,000 Micrograms of Aluminum Adjuvant Into the Body In Order to Attend School Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, Substantive Due Process Right to Life and Liberty, Free Exercise of Religion, and the Right to an Education

386. The preceding paragraphs are hereby realleged and incorporated herein by reference.

387. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the FORTIETH through FORTY-FIFTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

FORTY-SEVENTH CAUSE OF ACTION
Requiring Injection of GSK and Sanofi's Products for Which They Have Immunity from Liability for Injuries Violates the Substantive Due Process Right to Life and Liberty

388. The preceding paragraphs are hereby realleged and incorporated herein by reference.

389. Plaintiff is fully competent and able to make decisions based on the best interests of her child. GSK and Sanofi's DTaP/Tdap and IPV products can cause serious injury and death. While these products are not risk-free, federal law provides GSK and Sanofi near complete immunity from liability for injuries caused by their vaccine products. Plaintiff opposes injecting her child with these products. Requiring injection of DTaP/Tdap and IPV vaccine products in order to attend school over plaintiffs' objection, where the companies manufacturing and selling these products cannot be held accountable for injuries, is a violation of the substantive due process right to life and liberty.

390. Constitutional rights and the application of facts to ascertain whether such a right exists in a given situation can sometimes be perplexing. That should not be the case when it comes to determining whether the light of protection intended by the N.Y. and U.S. Constitutions and the Bill of Rights extends to the question of whether the state can require injection of a product where the for-profit company that makes and sells the product cannot be held accountable in a civil suit for injuries caused by the product. Setting this line will not prohibit a state from requiring injection of such a product. It will only prohibit the state from doing so during the period that the company that make and sell the product cannot be held financially accountable for the injuries caused by their product.

391. As explained in a dissenting opinion to a Supreme Court decision in which the majority affirmed that the 1986 Act provided complete immunity for design defect claims against pharmaceutical companies for harms caused by their vaccine products:

> [T]he majority's decision leaves a regulatory vacuum in which no one—neither the FDA nor any other federal agency, nor state and federal juries—ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers, given the lack of robust competition in the vaccine market, will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins. Nothing in the text, structure, or legislative history remotely suggests that Congress intended that result.

Bruesewitz, 562 U.S. at 275-76. This Supreme Court decision involved an injury arising after administering a tetanus, diphtheria and pertussis containing vaccine.

392. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injecting DTaP/Tdap and polio vaccine products into the body in order to attend school should be struck down as a violation of the substantive due process clause right to life and liberty because the pharmaceutical companies that manufacture and sell these products cannot be held financially accountable for harms caused by these products.

FORTY-EIGHTH CAUSE OF ACTION
Requiring Injection of GSK and Sanofi's Products for Which They Have Immunity from Liability for Injuries Violates the Fundamental Right to Bodily Integrity

393. The preceding paragraphs are hereby realleged and incorporated herein by reference.

394. Plaintiff is fully competent and able to make decisions based on the best interests of her child. GSK and Sanofi's DTaP/Tdap and IPV vaccine products can cause serious injury and death. While these products are not risk-free, federal law provides GSK and Sanofi near complete immunity from liability for injuries caused by their vaccine products. Plaintiff opposes injecting her child with these products. Requiring injection of DTaP/Tdap and IPV vaccine products in order to attend school over Plaintiff's objection, where the companies manufacturing and selling these products cannot be held accountable for injuries, is a violation of the substantive due process right to bodily integrity.

395. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require injecting DTaP/Tdap products into the body in order to attend school should be struck down as a violation of the fundamental right to bodily integrity because the parents and children harmed by these products cannot hold the pharmaceutical companies that manufacture and sell these products financially accountable for harms caused by these products.

FORTY-NINTH CAUSE OF ACTION
Requiring Injection of GSK and Sanofi's Products for Which They Have Immunity from Liability for Injuries Violates the Fundamental Right to Informed Consent

396. The preceding paragraphs are hereby realleged and incorporated herein by reference.

397. Plaintiff is fully competent and able to make decisions based on the best interests of her child. GSK and Sanofi's DTaP/Tdap and IPV vaccine products can cause serious injury and death. While these products are not risk-free, federal law provides GSK and Sanofi near complete immunity from liability for injuries caused by their vaccine products. Plaintiff opposes injecting her child with these products based on her review of the medical literature regarding these products. Requiring injection of DTaP/Tdap and IPV vaccine products in order to attend school over Plaintiff's objection, where the companies manufacturing and selling these products cannot be held accountable for injuries, is a violation of the fundamental right to informed consent.

398. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require injecting DTaP/Tdap products into the body in order to attend school should be struck down as a violation of the fundamental right to informed consent because the pharmaceutical companies that manufacture and sell these products cannot be held financially accountable for harms caused by these products.

FIFTIETH CAUSE OF ACTION
Requiring Injection of GSK and Sanofi's Products for Which They Have Immunity from Liability for Injuries Violates the Fundamental Right to Parental Choice

399. The preceding paragraphs are hereby realleged and incorporated herein by reference.

400. Plaintiff is fully competent and able to make decisions based on the best interests of her child. GSK and Sanofi's DTaP/Tdap and IPV vaccine products can cause serious injury and death. While these products are not risk-free, federal law provides GSK and Sanofi near complete immunity from liability for injuries caused by their vaccine products. Plaintiff opposes injecting her child with these products based on her review of the medical literature regarding these products. Requiring injection of DTaP/Tdap and IPV vaccine products in order to attend school over Plaintiff's objection, where the companies manufacturing and selling these products cannot be held accountable for injuries, is a violation of the fundamental right to parental choice.

401. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injecting DTaP/Tdap products into the body in order to attend school should be struck down as a violation of the fundamental right to parental choice because parents required to administer this product to their children cannot hold the pharmaceutical companies that manufacture and sell these products financially accountable for harms caused to their children by these products.

FIFTY-FIRST CAUSE OF ACTION
Requiring Injection of GSK and Sanofi's Products for Which They Have Immunity from Liability for Injuries Violates Fundamental Right to Bodily Integrity, Informed Consent, and Parental Choice, and the Substantive Due Process Right to Life and Liberty

402. The preceding paragraphs are hereby realleged and incorporated herein by reference.

403. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the FORTY-SEVENTH through FIFTIETH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

FIFTY-SECOND CAUSE OF ACTION

Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Substantive Due Process Right to Life and Liberty

404. The preceding paragraphs are hereby realleged and incorporated herein by reference.

405. Plaintiff and her child have a substantive due process right to life and liberty.

406. This right must include the ability to avoid injection of a product that can cause serious injury and death, especially where the studies needed to ascertain who will be susceptible to serious injury and death have not been undertaken. For some children the risk of serious injury or death is one hundred percent.

407. The studies needed to ascertain which children will suffer serious injury or death from injection of DTaP/Tdap products have not been conducted. The failure to conduct these studies is particularly egregious when the liability-free pharmaceutical companies selling these products to a captive market of 78 million American children have over $33 billion in vaccine revenue annually, and the CDC is spending over $5 billion annually to promote and purchase vaccines.

408. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Since the DTaP/Tdap vaccine products can cause death and serious injury, and the science needed to validate which children will be injured have not been undertaken, absent an actual emergency such as may occur during wartime, requiring her to administer this product to her child to attend school violates her and her child's substantive due process right to life and liberty.

409. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap to attend school should be struck down for violating the substantive

due process right to life and liberty because this product can cause serious injury and death and the studies required to assess which children will suffer such injury have not been undertaken.

FIFTY-THIRD CAUSE OF ACTION

Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Fundamental Right to Bodily Integrity

410. The preceding paragraphs are hereby realleged and incorporated herein by reference.

411. Plaintiff and her child have a fundamental right to bodily integrity.

412. As described in preceding paragraphs, which are incorporated herein by refence, this right must include the ability to avoid injection of a product that can cause serious injury and death, especially where the studies needed to ascertain who will be susceptible to serious injury and death have not been undertaken.

413. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Since the DTaP/Tdap vaccine products can cause death and serious injury, and the science needed to validate which children will be injured have not been undertaken, absent an actual emergency such as may occur during wartime, requiring Plaintiff to administer this product to her child to attend school violates Plaintiff's and her child's right to bodily integrity.

414. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap to attend school should be struck down for violating the fundamental right to bodily integrity because these products can cause serious injury and death and the studies required to assess which children will suffer such injury have not been undertaken.

FIFTY-FOURTH CAUSE OF ACTION

Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Fundamental Right to Informed Consent

415. The preceding paragraphs are hereby realleged and incorporated herein by reference.

416. Plaintiff and her child have a fundamental right to informed consent.

417. As described in preceding paragraphs, which are incorporated herein by refence, this right must include the ability to avoid injection of a product that can cause serious injury and death, especially where the studies needed to ascertain which children will be susceptible to serious injury and death have not been undertaken.

418. Plaintiff is fully competent and able to make decisions based on the best interests of her child. Since the DTaP/Tdap vaccine products can cause death and serious injury, and the science needed to validate which children will be injured have not been undertaken, absent an actual emergency such as may occur during wartime, requiring Plaintiff to administer this product to her child to attend school violates Plaintiff's and her child's right to informed consent.

419. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap to attend school should be struck down for violating the fundamental right to informed consent because these products can cause serious injury and death and the studies required to assess which children will suffer such injury have not been undertaken.

FIFTY-FIFTH CAUSE OF ACTION
Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Fundamental Right to Parental Choice

420. The preceding paragraphs are hereby realleged and incorporated herein by reference.

421. Plaintiff has a fundamental right to parental choice with regard to her child.

422. As described in preceding paragraphs, which are incorporated herein by refence, this right must include the ability to avoid injection of a product that can cause serious injury and death, especially where the studies needed to ascertain who will be susceptible to serious injury and death have not been undertaken.

423. Plaintiff is fully competent and able to make decisions based on the best interests of their child. Since the DTaP/Tdap vaccine products can cause death and serious injury, and the

science needed to validate which children will be injured have not been undertaken, absent an actual emergency such as may occur during wartime, requiring Plaintiff to administer this product to her child to attend school violates Plaintiff's and her child's right to parental choice.

424. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap to attend school should be struck down for violating the fundamental right to parental choice because these products can cause serious injury and death and the studies required to assess which children will suffer such injury have not been undertaken.

FIFTY-SIXTH CAUSE OF ACTION
Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Fundamental Right to Free Exercise of Religion

425. The preceding paragraphs are hereby realleged and incorporated herein by reference.

426. Plaintiff and her child have a fundamental right to free exercise of religion.

427. The studies needed to ascertain which children will suffer serious injury or death from injection of DTaP/Tdap products have not been conducted. The failure to conduct this science is particularly egregious when the liability-free pharmaceutical companies selling these products to a captive market of 78 million American children have over $33 billion in vaccine revenue annually, and the CDC is spending over $5 billion annually to promote and purchase vaccines.

428. If even a small fraction of this significant revenue were allocated toward conducting studies to determine which children were susceptible to serious injury or death from DTaP/Tdap, children could be saved from injury and death. It violates Plaintiff's religious beliefs to support a product that can cause serious injury and death to her child and other children that could have likely been avoided had some of the billions of dollars in sales of these products been allocated toward safety studies of these products.

429. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap to attend school should be struck down for violating the fundamental right to free exercise of religion because these products can cause serious injury and death and the studies required to assess which children will suffer such injury have not been undertaken.

FIFTY-SEVENTH CAUSE OF ACTION

Since DTaP/Tdap Can Cause Death or Serious Injury, Requiring Injection of These Products to Attend School Violates the Substantive Due Process Right to Life and Liberty and the Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, and Free Exercise of Religion

430. The preceding paragraphs are hereby realleged and incorporated herein by reference.

431. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the FIFTY-SECOND through FIFTY-SIXTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

FIFTY-EIGHTH CAUSE OF ACTION

Since the Safety Profile of DTaP/Tdap Has Not Been Established, Requiring Injection of These Products to Under Threat of Permanent Expulsion from School Violates Fundamental Right to Bodily Integrity

432. The preceding paragraphs are hereby realleged and incorporated herein by reference.

433. Plaintiff and her child have a fundamental right to bodily integrity.

434. The fundamental right to bodily integrity must include being free from having, under penalty of expulsion from school, to be injected with a product where the most commonly claimed serious injuries consumers assert are caused by the product have not been studied to ascertain if they are actually caused by the product; and moreover, where the product has never been evaluated for whether it can cause cancer, mutate genes, or cause infertility despite evidence indicating it may cause these conditions.

435. DTaP/Tdap are medical products manufactured by pharmaceutical companies that are injected into muscle tissue intended, through chemical manipulation, to generate a long-term immunological change in the body. Studies have not been undertaken to determine whether there is a causal relationship between these products and most of the dozens of serious injuries that the CDC and HHS assert are the most commonly claimed injuries from these products. Furthermore, despite the fact that there are studies to support that aluminum can cause cancer, mutate genes, and cause infertility, and that DTaP/Tdap contain aluminum which is then injected into the body, these products have never even been evaluated for whether they can cause cancer, mutate genes or cause infertility.

436. There is no excuse for not conducting these studies. These products have been licensed for dozens of years and the liability-free pharmaceutical companies that sell these products to a captive market of 78 million American children generate over $33 billion in vaccine revenue annually and the CDC spends over $5 billion annually to promote and purchase vaccines.

437. Wherefore, the portions of PHL § 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the fundamental right to bodily integrity because the studies needed to determine which serious injuries are actually caused by these products have not been undertaken.

FIFTY-NINTH CAUSE OF ACTION
Since the Safety Profile of DTaP/Tdap Has Not Been Established, Requiring Injection of These Products to Under Threat of Permanent Expulsion from School Violates Fundamental Right to Informed Consent

438. The preceding paragraphs are hereby realleged and incorporated herein by reference.

439. Plaintiff and her child have a fundamental right to informed consent.

440. As described in preceding paragraphs, which are incorporated herein by refence, the studies needed to determine what injuries are caused by DTaP/Tdap have not been conducted,

despite billions in revenue in sales from these products and billions spent in promoting and purchasing these products by the CDC and HHS.

441. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the fundamental right to informed consent because the studies needed to determine which serious injuries are actually caused by these products have not been undertaken.

SIXTIETH CAUSE OF ACTION
Since the Safety Profile of DTaP/Tdap Has Not Been Established, Requiring Injection of These Products to Under Threat of Permanent Expulsion from School Violates Fundamental Right to Parental Choice

442. The preceding paragraphs are hereby realleged and incorporated herein by reference.

443. Plaintiff and her child have a fundamental right to parental choice.

444. As described preceding paragraphs, which are incorporated herein by refence, the studies needed to determine what injuries are caused by DTaP/Tdap have not been conducted, despite billions in revenue in sales from these products and billions spent in promoting and purchasing these products by the CDC and HHS.

445. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the fundamental right to parental choice because the studies needed to determine which serious injuries are actually caused by these products have not been undertaken.

SIXTY-FIRST CAUSE OF ACTION
Since the Safety Profile of DTaP/Tdap Has Not Been Established, Requiring Injection of These Products to Under Threat of Permanent Expulsion from School Violates Substantive Due Process Right to Life and Liberty

446. The preceding paragraphs are hereby realleged and incorporated herein by reference.

447. Plaintiff and her child have a substantive due process right to life and liberty.

448. As described in preceding paragraphs, which are incorporated herein by refence, the studies needed to determine what injuries are caused by DTaP/Tdap have not been conducted, despite billions in revenue in sales from these products and billions spent in promoting and purchasing these products by the CDC and HHS.

449. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the substantive due process right to life and liberty because the studies needed to determine which serious injuries are actually caused by these products have not been undertaken.

SIXTY-SECOND CAUSE OF ACTION
Since the Safety Profile of DTaP/Tdap Has Not Been Established, Requiring Injection of These Products to Under Threat of Permanent Expulsion from School Violates Fundamental Right to Bodily Integrity, Informed Consent, Parental Choice, and the Substantive Due Process Right to Life and Liberty

450. The preceding paragraphs are hereby realleged and incorporated herein by reference.

451. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the FIFTY-EIGHTH through SIXTY-FIRST CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

SIXTY-THIRD CAUSE OF ACTION
Retaining a Non-Religious Exemption to Vaccination While Eliminating a Religious Exemption Violates the Free Exercise Clause

452. The preceding paragraphs are hereby realleged and incorporated herein by reference.

453. Section 2164 of the Public Health Law infringes upon religious freedom because it provides a non-religious exemption from vaccination – e.g., a limited medical exemption – without affording a religious exemption.

454. Freedom of Religion is the first and primary fundamental right of Americans, and the right of free exercise is enshrined in the Bill of Rights before any others fundamental right is mentioned. Voluminous First Amendment jurisprudence requires strict scrutiny of any action that burdens free exercise, especially when it involves the elimination of a right to practice one's religion. In *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993), addressing another law specifically designed to eliminate a form of free exercise, the Supreme Court reiterated that "[a] law burdening religious practice that is not neutral or not of general application must undergo the most rigorous of scrutiny."

455. The repeal of the religious exemption for tetanus, diphtheria, and pertussis containing vaccines from PHL § 2164 is clearly not neutral when it was specifically intended to eliminate a religious exemption for these vaccines.

456. Upon repeal of the religious exemption from PHL § 2164, this section infringes upon religious freedom regarding compulsory injection of tetanus, diphtheria, and pertussis containing vaccines over religious based objections because it provides a non-religious exemption for these products; that is, it provides a limited medical exemption, without affording a religious exemption. The U.S. Supreme Court has held that "in circumstances in which individualized exemptions from a general requirement are available, the government 'may not refuse to extend that system to cases of 'religious hardship' without compelling reason.'" *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 537 (1993) *see also Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359, 364 (3d Cir. 1999) ("refusal to make religious exemptions from its … policy should be reviewed under strict scrutiny because the Department makes secular exemptions to its policy").

457. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school attendance is absent with regard to the pertussis vaccine.

458. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school attendance is absent with regard to the tetanus vaccine.

459. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school attendance is absent with regard to the diphtheria vaccine.

460. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school attendance is absent with regard to the polio vaccine.

461. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require vaccination for DTaP/Tdap and IPV to attend school should be struck down for violating the free exercise clause since it recognizes a non-religious exemption to receiving these products without providing for a religious exemption to receiving these products.

SIXTY-FOURTH CAUSE OF ACTION
The Totality of the Facts Regarding DTaP/Tdap Products Renders the Requirement that this Product be Injected Six Times into the Body of a Child in order to Attend School a Violation of the Fundamental Right to Bodily Integrity

462. The preceding paragraphs are hereby realleged and incorporated herein by reference.

463. Prior to eighteen years of age, PHL § 2164 and 10 NYCRR § 66-1.1(f) prohibit a student from attending school in New York without receiving five doses of DTaP and one dose of Tdap, or an appropriate number of catch-up doses.

464. Striking a balance between individual liberty and permitting a state's compelling interest to infringe on that liberty in the least restrictive means possible, can be a delicate balance. The lines are often gray. Muddied through complexity. When it comes to whether individual liberty should be trampled upon by requiring DTaP and Tdap vaccines to attend school, there are complexities. What is not complex however is that (once stripped of histrionics and false assumptions) requiring Plaintiff's child to be injected with this product to attend school is a violation of their fundamental rights.

465. The facts are as follows with regard to these products:

a. Injecting a child with DTaP and Tdap does not prevent a child from becoming infected with and transmitting:

i. pertussis (and in fact renders the child susceptible to repeated pertussis infection without presenting symptoms);

ii. tetanus (because it is not contagious from person-to-person); and

iii. diphtheria (because these products do not create antibodies to the diphtheria bacteria, but rather only a toxin it sometimes releases);

b. The incidence of tetanus and diphtheria have remained at or near zero in the years before and after requiring vaccination for these infections to attend school under New York State law, and the incidence of pertussis in fact increased after requiring vaccination for this infection to attend school under New York State law;

c. The pharmaceutical companies which manufacture and sell all DTaP and Tdap vaccines in the United States – GSK and Sanofi – have immunity from liability for injuries caused by these products, thereby eliminating the financial incentive

companies have to assure the safety of their products either pre-or-post licensure;

d. Irrespective of advances in technology or medical science, no design defect claim can ever be asserted against GSK and Sanofi for failing to improve the safety of their tetanus, diphtheria, or pertussis containing vaccines;

e. The health authority responsible for vaccine safety, HHS, has a structural conflict in fulfilling its vaccine safety duties since it is responsible to increase vaccine uptake and literally defend against any claim that these vaccines cause injuries in court, and HHS has conceded in federal court that it has failed to fulfill its basic duties under the "Mandate for safer childhood vaccines";

f. None of the DTaP or Tdap vaccines were licensed based on clinical trials that included a control group that received a placebo (or which used another product or substance as a control which was licensed based on a placebo-controlled clinical trial), and the safety review period after injection in these trials was typically only six months;

g. The only natural experiment of tetanus, diphtheria and pertussis containing vaccines that included an unvaccinated control group found that those receiving this vaccine in the first six months of life died at ten times the rate as those children that received no vaccines during this period;

h. Studies have *not* been conducted to determine whether DTaP/Tdap vaccines cause (i) what the CDC asserts are the most commonly claimed injuries from this product, including acute disseminated encephalomyelitis, ataxia, autism, bell's palsy, chronic inflammatory demyelinating polyneuropathy, chronic

urticaria, encephalitis, Guillain-Barre syndrome, infantile spasms, multiple sclerosis, myocarditis optic neuritis, opsoclonus myoclonus syndrome, seizures, scrum sickness, and transverse myelitis, (ii) cancer, infertility, or genetic defects, or (iii) the numerous serious conditions listed on the package insert for these vaccines that GSK and Sanofi have a basis to believe are actually *caused* by these products;

i. It is medically accepted that DTaP and Tdap can cause serious injury, but the studies to identify which children will suffer a serious injury from these products have not been undertaken; and

j. Studies demonstrate that the tens of thousands of .1 to 1 micron-sized particles of aluminum hydroxide or aluminum phosphate injected into the body with each dose of DTaP and Tdap are carried by the immune system and deposited into various parts of the body, notably brain tissue, where they can cause serious long term health issues.

466. Given the foregoing, if this product can be mandated to be injected into the body of a child six times under duress of expulsion from school, then the liberty guaranteed by the constitution is no longer meaningful. It will affirm that rights can be abrogated based on populist norms affirmed by moneyed interests, rather than what the evidence can support. That is not liberty.

467. It is for when those elected by the majority pass laws affirming majority views that the rights enshrined in our Constitution and Bill of Rights become meaningful. It is for those views that are considered unpopular and held by those that are often demonized and marginalized. It is in those moments that the courts give life and meaning to constitutional rights and safeguards. Not

only to protect the minority, but to protect the principles in that founding covenant which protect all Americans. As Judge Irving R. Kaufman, Second Circuit, aptly wrote decades ago: "Tolerance of the unorthodox and unpopular is the bellwether of a society's spiritual strength."

468. Censorship of any assertions regarding vaccines that are in any manner negative have become the norm. It is considered off limits to question or even demand to see the evidence which underpins claims regarding vaccines. It is for this precise reason that this Court must, to sow justice, consider the products at issue in this complaint based on actual proof – not preconceived notions, assumptions, or the brandishing of credentials. While these products hold an almost mythological status and mental sway on the minds of the average American, there should not be special treatment accorded to the liability-free (but not risk-free) products at issue in this complaint.

469. Consider that there are approximately 1,400 known species of human pathogens, and almost none of them have a vaccine. (https://www.health.ny.gov/statistics/diseases/communicable/2017/docs/cases.pdf) (In 2017, there were 200,816 cases of 47 different communicable diseases which New York law requires medical providers to report but which have no vaccine). Yet, there is no hysteria regarding these infections. That is, until there is a vaccine product or the prospect of a vaccine on the horizon.

470. Plaintiff asks that the issues presented in this complaint turn on proof and evidence, not on the often repeated but never supported claim that DTaP/Tdap vaccines are "safe and effective" and that the "science is settled." Unless the claims in the preceding paragraphs above are untrue, it is difficult to see how compelling injection of these products under penalty of exclusion from school in New York can be constitutional. However, if this Court unquestioningly submits to the generally accepted narrative regarding these products without demanding proof,

then the precedent it will set is that there is no right that cannot be pushed aside when there is a sufficiently one-sided financial interest that is able to drive a populist narrative based on fear, rather than objective facts.

471. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injecting DTaP/Tdap products into the body in order to attend school should be struck down as a violation of the right to bodily integrity.

SIXTY-FIFTH CAUSE OF ACTION
The Totality of the Facts Regarding DTaP/Tdap Products Renders the Requirement that this Product be Injected Six Times into the Body of a Child in order to Attend School a Violation of the Fundamental Right to Informed Consent

472. The preceding paragraphs are hereby realleged and incorporated herein by reference.

473. Plaintiff and her child have a fundamental right to informed consent and the preceding paragraphs are hereby incorporated by reference as if fully set forth herein.

474. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the fundamental right to informed consent.

SIXTY-SIXTH CAUSE OF ACTION
The Totality of the Facts Regarding DTaP/Tdap Products Renders the Requirement that this Product be Injected Six Times into the Body of a Child in order to Attend School a Violation of the Fundamental Right to Parental Choice

475. The preceding paragraphs are hereby realleged and incorporated herein by reference.

476. Plaintiff and her child have a fundamental right to parental choice and the preceding paragraphs are hereby incorporated by reference as if fully set forth herein.

477. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the fundamental right to parental choice.

SIXTY-SEVENTH CAUSE OF ACTION

The Totality of the Facts Regarding DTaP/Tdap Products Renders the Requirement that this Product be Injected Six Times into the Body of a Child in order to Attend School a Violation of Substantive Due Process Right to Life and Liberty

478. The preceding paragraphs are hereby realleged and incorporated herein by reference.

479. Plaintiff and her child have a substantive due process right to life and liberty, and the preceding paragraphs are hereby incorporated by reference as if fully set forth herein.

480. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f) which require injection of DTaP or Tdap to attend school should be struck down for violating the substantive due process right to life and liberty.

SIXTY-EIGHTH CAUSE OF ACTION

The Totality of the Facts Regarding DTaP/Tdap Products Renders the Requirement that this Product be Injected Six Times into the Body of a Child in order to Attend School a Violation of the Fundamental Right to Bodily Integrity, Informed Consent, and Parental Choice, and the Substantive Due Process Right to Life and Liberty

481. The preceding paragraphs are hereby realleged and incorporated herein by reference.

482. To the extent the impingement upon multiple constitutional rights, as opposed to any one right individually, heightens the compelling state interest required to infringe on these rights, the allegations pled in the SIXTY-FOURTH through SIXTY-SEVENTH CAUSES OF ACTION are hereby pled collectively as if fully set forth herein.

PRAYER FOR RELIEF

Wherefore, the Plaintiff respectfully requests that this Court:

A. On the first through fifteenth, fortieth through sixty-second, and sixty-fourth through sixty-eighth causes of action, grant an injunction prohibiting the expulsion of a child from school for not being injected with a pertussis-containing vaccine;

B. On the sixteenth through twenty-third, fortieth through sixty-second, and sixty-fourth through sixty-eighth causes of action, grant an injunction prohibiting the expulsion of a child from school for not being injected with a diphtheria-containing vaccine;

C. On the twenty-fourth through thirty-first, fortieth through sixty-second, and sixty-fourth through sixty-eighth causes of action, grant an injunction prohibiting the expulsion of a child from school for not being injected with a tetanus-containing vaccine;

D. On the thirty-second through thirty-ninth, fortieth through sixty-second, and sixty-fourth through sixty-eighth causes of action, grant an injunction prohibiting the expulsion of a child from school for not being injected with a polio vaccine;

E. On the fortieth through forty-sixth causes of action, declare that DTaP/Tdap products contain aluminum adjuvant and grant an injunction prohibiting the expulsion of a child from school for not being injected with a product that contains aluminum adjuvant;

F. On the forty-seventh through fifty-first causes of action, declare that the manufacturers of DTaP/Tdap and IPV products have immunity from liability for design defect claims and grant an injunction prohibiting the expulsion of a child from school for not being injected with a product whose manufacturer is immune from liability for design defect claims;

G. On the fifty-second through fifty-seventh causes of action, declare that all DTaP/Tdap products can cause death or serious injury and grant an injunction prohibiting the expulsion of a child from school for not being injected with a product that can cause death or serious injury;

H. On the fifty-eighth through sixty-second causes of action, declare that the safety profile of each DTaP/Tdap product has not been determined and grant an injunction prohibiting

the expulsion of a child from school for not being injected with a product whose safety profile has not been determined;

I. On the sixty-third cause of action, grant an injunction prohibiting the expulsion of a child from school for not being injected with a product when their parents oppose such injection, based on their religious beliefs, if there is a non-religious exemption which permits attending school without such injection;

J. On the sixty-fourth through sixty-eighth causes of action, grant an injunction prohibiting the expulsion of a child from school for not receiving an injection of a DTaP/Tdap product;

K. Grant such further relief as the Court deems necessary and proper; and

L. Award attorneys' fees and costs of this action.

Dated: June 15, 2021

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